- VOLUME 3 -

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, Plaintiffs, vs. EAGLE PHARMACEUTICALS INC., Defendant.	:	CIVIL ACTION NO. 18-823-CFC-JLH (Consolidated)
PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC, Plaintiffs, vs. AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, et al., Defendants.	:	CIVIL ACTION NO. 18-2032-CFC-CJB

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Wilmington, Delaware
Friday, July 9, 2021
8:56 o'clock, a.m.

- - -

BEFORE: HONORABLE COLM F. CONNOLLY, Chief Judge

- - -

Valerie J. Gunning
Official Court Reporter

APPEARANCES:

FARNAN LLP
BY: MICHAEL E. FARNAN, ESQ.

-and-

DECHERT LLP
BY: MARTIN J. BLACK, ESQ.,
ROBERT RHOAD, ESQ.
SHARON GAGLIARDI, ESQ.,
BLAKE GREENE, ESQ. and
LUKE REILLY, ESQ.
(Philadelphia, Pennsylvania)

Counsel for Plaintiffs
Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC

YOUNG, CONAWAY, STARGATT & TAYLOR, LLP
BY: ANNE SHEA GAZA, ESQ. and
SAMANTHA G. WILSON, ESQ.

-and-

GOODWIN PROCTER LLP
BY: HUIYA WU, ESQ.
(New York, New York)

Counsel for Defendants
Amneal Pharmaceuticals of New York, LLC, et al.

POTTER ANDERSON & CORROON LLP
BY: DAVID E. MOORE, ESQ. and
BINDU A. PALAPURA, ESQ.

-and-

APPEARANCES (Continued):

KIRKLAND & ELLIS LLP
BY: BRYAN S. HALES, ESQ.
(Chicago, Illinois)

-and-

KIRKLAND & ELLIS LLP
BY: JEANNA M. WACKER, ESQ. and
SAM KWON, ESQ.
(New York, New York)

Counsel for Defendant
Eagle Pharmaceuticals Inc.

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P R O C E E D I N G S

(Proceedings commenced in the courtroom, beginning at 8:56 a.m.)

THE COURT: Good morning, everybody. Please be seated. All right.

MS. WU: Your Honor, yesterday I told you that defendants would be calling two experts, Dr. Winter, the peptide expert, and Dr. Marais, the expert in statistics. We've looked at the transcript overnight. The experts are ready to go, but in an effort to further streamline the case, we will not be calling Dr. Winter and Dr. Marais today, perhaps in the future, when we'll be proceeding on the Amneal product.

So with that, I think I will turn it to Mr. Lasky to introduce the also shortened video testimony of, I think, four witnesses.

THE COURT: All right. Thank you very much.

MR. BLACK: I just -- just for the record, on Dr. Marais, there's one point that he made in his report at his deposition which Dr. Kirsch relied on in his expert report, so it's in his report, which Dr. Kirsch will be testifying on, relying on an expert out-of-court statement material in the case. And we're just putting you on notice,

we put them on notice we're going to do that, and we've asked them to keep Dr. Marais in the jurisdiction. If they feel that that is inadmissible, I don't see how it could be under 703. We're just putting the marker down.

MS. WU: We'll take a look at that. Dr. Marais is not changing his travel plans, so let me look and see what Mr. Black's position is.

THE COURT: Meaning he's here and could testify potentially?

MS. WU: Yes.

THE COURT: Thank you very much.

MR. HALES: I would, Your Honor, if an expert is not going to answer an opinion, it seems like it's hearsay for Dr. Kirsch to respond to an un-presented opinion.

MR. BLACK: Well, it would be hearsay, but experts may rely on hearsay, and particularly when it's referred to in the expert who is going to testify to his report. We can address it when we get there. But I'm putting them on notice, if they are making the witness unavailable --

THE COURT: They are not making him unavailable. We'll deal with it.

MR. BLACK: One other housekeeping issue, Your Honor. Mr. Rhoad would like to approach.

THE COURT: All right.

(Sidebar conference held as follows.)

MR. RHOAD: Your Honor, I just wanted to raise this at sidebar. It involves a medical condition of Dr. Kannan.

We just wanted to give you a heads-up that he has developed a condition undiagnosed, getting therapy, but like out of blue, he gets like really sharp pain in his foot that like radiates up his legs and he says when that happens, you know, he can't sit down, and I just raise it because who knows?

He says it comes unexpectedly and he hasn't had an issue, but if it comes up, I just want to let you know that, you know, if it happens to strike him while he's on the witness stand, we may have to take a break.

I don't know. I just wanted -- so it didn't happen out of the blue. I wanted to do it at sidebar so it wouldn't be associated with his medical condition, put.

THE COURT: I appreciate you doing that. If he stands up all of a sudden in court, it may become public what's going on.

MR. RHOAD: No. I just mean I didn't want to say it in public if it didn't happen.

THE COURT: Perfect. I appreciate you doing that.

MR. HALES: We understand, too.

THE COURT: Are you all ready timewise and all that?

MR. RHOAD: Yes, Your Honor. Yes, Your Honor.

THE COURT: I told you there may be some flexibility built in. I think both sides have done -- I appreciate the jobs you've done so far and that goes to all lawyers, even if I've ever ragged on one lawyer in particular for doing something. Every single lawyer deserves kudos for the manner in which they have presented the case. All right?

MR. BLACK: Thank you, Your Honor.

(End of sidebar conference.)

THE COURT: Ms. Wacker?

MS. WACKER: We have a list of exhibits.

THE COURT: I'm comfortable with the reading as long as plaintiff is. Sorry. Not reading. Yes.

MS. WACKER: We appreciate that. Just to note for the record, there is one that is crossed out and I've already spoken to your clerk about it, DTX-29, and the parties know that and we're all in agreement on it.

THE COURT: That it should not be admitted?

MS. WACKER: It should not be admitted. At the back, for the convenience of the Court, we've attached the demonstratives that we've agreed to admit as well.

THE COURT: Okay.

MS. WACKER: The ones we've gone over in the testimony.

THE COURT: All right. Sounds good. Just so I will know, did you admit into evidence or substantive evidence, rather, the slides that I was so confused about? I think I have clarity now, but just so I know?

MS. WACKER: It was during the Chyall testimony from yesterday?

THE COURT: Yes.

MR. BLACK: I don't believe the slides have been admitted in as substantive evidence other than my markup, which was evidence that that was admitted.

THE COURT: Okay.

MR. BLACK: But I don't think the slides should be admitted. There's a lot of argument on them and I know it's a bench trial. It might be helpful to the Court to have them if you already have them, but they are not technically in evidence, particular the Chyall slides, which are missing and matching different pieces.

THE COURT: Right. But in terms of saving me time, right, if I was trying to say in an opinion that at a subsequent date that certain data was submitted, is it fair instead of me going back and looking at DTX-7, whatever it was if it's cited in the slide, I could just basically look at the slide and say other than the far right column, it's

very clear that was not part of your original underlying exhibit, I could just take the information?

MR. BLACK: I would say the only -- yes. I think all the other slides --

THE COURT: Take the information from the slide.

MR. BLACK: Right. All the other slides in the case had designations which were pretty clear which exhibit it came from, so you would be able to match them up. The Chyall slide, a little bit more difficult. All the other ones I think work fine.

THE COURT: I got clarity eventually that there's basically three of the four slides. There were two exhibits being referenced and other than the notations, which I think are very clear, and the testimony made it clear, the underlying data I could just pull from that slide and safely cite the exhibit that's cited in the slide?

MS. WACKER: I think that's right.

MR. LOEB: Your Honor, we don't think that any of the numbers in the tables are inaccurate, transcribed incorrectly.

However, as a subset of all the information that was provided in the declaration --

THE COURT: Right. There's more information.

MR. LOEB: Dr. Kirsch is going to testify about

the information in a holistic way. So, hopefully, it will be clear what's coming from the deposition.

THE COURT: Back to interpretation issue. I got it. I hear you.

MR. BLACK: The exhibit numbers are correct. My guess is if you refer to that specific piece, your law clerk might want to go check and make sure the actual exhibit will be in just to make sure it's all right, but I think it should be fine.

THE COURT: All right. Thank you, all.

Okay. What's next? What I'm going to do is, so we were handed up by Ms. Wacker without objection the document entitled exhibits to be admitted and along with slides and along with two attachments.

The first attachment is four pages and it's marked DDX7-1, DDX-7-2, DDX-7-3 and DDX-7-4.

The second attachment is marked PTX-1442. It was a demonstrative exhibit and markings were made to it during the course of the trial by Mr. Black and then those markings were used to question the witness, and my understanding is that this document would be adjustments made during the trial, has been admitted as substantive evidence.

Is that correct? Mr. Black, that's correct?

MR. BLACK: Yes, Your Honor.

THE COURT: And that has already been admitted. Right?

MS. WACKER: As part of the submission that was given to Your Honor. None of the exhibits from yesterday were officially admitted.

THE COURT: All right. And then the second attachment, which I mentioned had the four pages, that had been admitted as substantive evidence.

MS. WACKER: That's correct, Your Honor.

THE COURT: Okay.

MS. WACKER: The parties have agreed to admit that.

MR. BLACK: A summary table.

THE COURT: All right. So I mentioned, for instance, the four pages on the attachment. Are they listed in the cover document?

MS. WACKER: Yes, they are.

THE COURT: They are. And is the document that was the second attachment, is it somehow identified in the cover document with the list of the exhibits?

MS. WACKER: Yes.

THE COURT: What is it identified as?

MR. BLACK: We gave it a PTX number last night. It's right on the document there.

THE COURT: Okay. PTX-1442, that's something

new you have added?

MR. BLACK: Correct.

MS. WACKER: They added the numbers.

THE COURT: I get it. I think I'm good then.

All right. And then I'm going to mark as Court Exhibit 1, going to mark it with my handwriting. Court Exhibit 1 is the list of exhibits to be admitted along with the two attachments. It's now formally part of the record. From that we'll now have I think a clear record. All right.

MS. WACKER: Thank you, Your Honor.

THE COURT: Thank you.

MR. BLACK: One other very small matter, Your Honor.

THE COURT: Yes?

MR. BLACK: The definitions. We agree with all the definitions they have. We have two clarifications that we're filing by letter this morning.

THE COURT: All right. Thank you. All right. MR. Lasky?

MR. LASKY: Good morning, Your Honor. Defendants call by deposition Cara English from Par's regulatory department.

Ms. English was deposed in her personal capacity and also pursuant to Federal Rule of Civil Procedure

30(b)(6) on behalf of Par on the topic of the April 2014 label for Vasostrict, including the identity of any individuals who contributed to the label and their role.

This testimony, or at least defendants' designations, are relevant to the counterclaim of inequitable conduct.

THE COURT: Thank you.

MR. LASKY: May we approach with the binders?

THE COURT: Yes.

MR. LASKY: The time. For defendants, one minute, 23. For Par, three minutes, 40, for a total of five minutes and three.

MR. HALES: I apologize. There were some counter-designations withdrawn. For defendants, one minute, 23. For Par, one minute 21, for a total time of two minutes, 44.

THE COURT: All right. Thank you.

(The videotaped deposition of Carla English was played as follows.)

"Question: Good morning. Could you please state full your name for the record.

"Answer: Cara English.

"Question: And are you prepared to testify on the identity of any individuals who contributed to the label?

"Answer: Yes, to the best of my knowledge.

"Question: I've handed you what's been as marked Exhibit 7. The Bates number for this document is Par VASO-001-001573. It ends with 15586.

"Do you recognize this document.

"Answer: Yes.

"Question: Is this the originally approved 2014 Vasostrict label?

"Answer: This is the approval letter that was included with the FDA approval letter for NDA 204485.

"Question: So who contributed to this label?

"Answer: To the text, the content, that's within the label?

"Question: And the substance.

"Answer: The substance?

"Question: And the factual basis.

"Answer: Right. I, you know, I can't say for any certainty. It's a collective effort. The sections come from -- are written by different various groups and departments submitted to FDA and then ultimately approved. So I can't say for certain who contributed to which sections.

"There isn't --

"Question: I'm not divvying it up by different sections.

"Answer: Right.

"Question: My question is directed to this whole label. Who contributed the drafting of this approved label?

"Answer: There's -- I don't know. There's no way of me knowing who by name contributed to this label.

"Question: Does Par have any knowledge regarding the identity of any person that has contributed to the drafting of this label?

"Answer: Par does not -- there's -- there's no document that represents which individual, which person, contributed to the sections of this label.

"Question: Does Par have any knowledge whatever regarding any person whatsoever who has contributed to the drafting and preparing of this label?

"Answer: To Par's knowledge, Par does not believe to have any knowledge of who contributed to the sections of this label to the best of my understanding."

THE COURT: All right. I'm sorry. Can we stop everything?

(Pause.)

THE COURT: Okay. I mean, I guess I didn't really fully appreciate this. So basically, I'm following the transcript and I get lost. Is it because lines have now

been cut from what you handed me?

MR. BLACK: Yes, Your Honor. It looks like we had given them cuts to the plaintiffs' counter-designations and I have a revised clip report that has those cuts.

I think the binder --

MR. LASKY: I believe the cuts came in late last night. Perhaps the bind binders were not updated. I wasn't aware. Do you have the revised?

THE COURT: The other thing is just for the record, I've been reading things that aren't going to be in evidence and I'm also lost as to kind of where we are.

And then also -- are you going to -- what have you been doing? Have you been introducing as exhibits the excerpted transcripts or are you relying solely on the court reporter's reporting of the recording of the played deposition?

MR. HALES: What we've handed up to the Court each time has been intended to be the transcript of just the clips and then I've had courts do that both ways.

THE COURT: Well, what have you all been doing? Have you been adding? For instance, the deposition transcripts that you played yesterday, did somebody enter them into evidence?

MR. HALES: No, I don't think so.

THE COURT: Okay.

MR. HALES: But we can take that approach.

THE COURT: So you want me to go and read it? It would be a lot easier unless there's an objection and I will entertain it to have as an exhibit the transcript of the deposition.

Now, I realize that that, the deposition transcript, the court reporter may have gotten it inaccurate and we would rely on typically, right, the court reporter here, but my experience, especially in ANDA trials, everybody just agrees to use the original transcript. What do you all want to do?

MR. HALES: We would be fine with that approach.

MR. BLACK: Yes, Your Honor.

THE COURT: Okay. So can you then some time later today arrange to have all the transcripts that were cited yesterday identified as exhibits and move them into evidence and then I will rely on that.

MR. HALES: Yes.

THE COURT: And then for this particular transcript, can we have at some point a version produced that reflects what's being played?

MR. BLACK: Yes.

MR. HALES: Yes.

THE COURT: One other question. Was this video or was it not?

MR. HALES: It was not video.

THE COURT: So when you put up the document on the screen that's being discussed by the deponent, it has been done after the fact by an IT person?

MR. HALES: Correct.

MR. LOEB: Your Honor, I have a transcript that is going to match the video.

THE COURT: That would be great. Then you all handed up eight or nine notebooks to the clerk. I guess these are going to be for other depositions that you are going to play?

MR. BLACK: Yes.

THE COURT: Do we know if they're --

MS. WACKER: We're double-checking that right now.

THE COURT: Okay. Great. Thank you.

(The videotaped deposition resumed.)

"Answer: Par's knowledge, Par does not believe to have any knowledge of who contributed to the sections of this label to the best of my understanding.

"Question: And just to be clear, I'm not talking about just putting together the label itself. I'm talking about the consent and substance thereof. You understood that, correct?

"Answer: Correct, I understand that."

(End of videotaped deposition.)

THE COURT: Okay. Thank you. Given the state of the world, this is the first I've encountered audio only depositions being played at trial.

I think I'm going to make it a practice going forward, and I'm sure everybody in this court will be back in front of me in some other case, I recognize you all. I'm personally good with just transcripts if you are just going to be listening. I think the video is helpful in terms of demeanor, assessment, credibility, but if I'm just listening, consider talking about just submitting transcripts.

And I'm not encouraging you to try the case that way. I realize sometimes you don't have a choice. You have to play things. You have to go by deposition.

MR. HALES: The good news, Your Honor, I think these are one-third of the length they were yesterday.

THE COURT: That's good. That's fine. That suggests to me that you can -- I have not heard an application that says you were unable to present your case because of the time limitation.

MR. LASKY: Defendants move to admit DTX-30 that was mentioned in English's testimony.

THE COURT: Any objection?

MR. BLACK: No objection, Your Honor.

THE COURT: All right. It's admitted.

(DTX-30 was admitted into evidence.)

MR. LASKY: Next, the defendants call by deposition designation Craig Kenesky.

Craig Kenesky was the prosecuting attorney for the patents-in-suit as well as the '239 patents and the other Par patents that have been discussed in the case and he was deposed in his personal capacity. His testimony is relevant to defendants' inequitable conduct counterclaim.

THE COURT: All right. Could I have a transcript? Okay. Thank you.

(The videotaped deposition of Craig Kenesky was played as follows.)

"Would counsel introduce themselves."

"MR. LASKY: My name is Benjamin Lasky. I'm from Kirkland & Ellis, and I'm here on behalf of the defendant Eagle Pharmaceuticals.

"MS. CADE: Ashley Cade, also with Kirkland & Ellis, on behalf of defendant Eagle Pharmaceuticals.

"MR. CARLSON: Erik Carlson.

"MS. GAGLIARDI: Sharon Gagliardi, Dechert LLP, on behalf of the plaintiff.

"Question: Could you please state your full name and address for the record.

"Answer: My full name is Dr. Craig Scott

Kenesky. Address, 190 Donaldson Avenue, Rutherford, New Jersey, 07070.

"Question: Have you ever had your deposition taken before?

"Answer: No.

"Question: Have you ever taken a deposition before?

"Answer: No.

"Question: Now, part of your experience at Wilson Sonsini is described here, and your experience is portfolio development strategy; is that correct?

"Answer: That is correct.

"Question: Were you involved in portfolio development strategy on behalf of Par Pharmaceutical for vasopressin?

"Answer: Yes.

"Question: Dr. Kenesky, we've handed a copy of a document that has been marked as Kenesky Exhibit 3. It is a copy of excerpted file history for U.S. Patent No. 9,744,239.

Okay. Were you involved in the prosecution of U.S. Patent No. 9,744,239?

"Answer: Yes.

"Question: And were you the lead outside counsel in prosecution of the '239 patent?

"Answer: Yes.

"Question: And you understand that the '239 patent was filed and prosecuted under the AIA provisions, correct?

"Answer: That is what I recall, yes.

"Question: Okay. And so the Examiner's rejection in this office action is under 35 U.S.C. Section 102 and 103 under post-AIA Patent Act, correct?

"Answer: That is what the document says.

"Question: If we turn over to the page to the page ending in 8326 of the office action, the Examiner states that claims 16 to 28 and 30 are rejected under 35 U.S.C. 102(a)(1) as anticipated by or in the alternative under 35 U.S.C. 103 as obvious over the FDA label for Vasostrict NPLU PTO '0892 published April 2014; do you see that?

"Answer: I see where the document says that.

"Question: And if we turn, please, back to the page ending in '8326, which is the page we were talking about earlier where the Examiner explained or began explaining the rejection of the Vasostrict label, we see from the second paragraph down, the Examiner provides a description of what the FDA label teaches, correct?

"Answer: The document has a statement regarding, quote, the FDA label teaches, et cetera. Whether

that is what the FDA label teaches is something that I'm not going to opine on.

"Question: You understood when you reviewed this office action, October 21, 2015, office action, in prosecution of the '239 patent that the subject matter identified on page 8326 was subject matter that the Examiner was relying on in alleging that the FDA label anticipated or rendered obvious the pending claims of the application, correct?

"Answer: Yes, I understood that the Examiner was relying on these allegations.

"Question: So the document in Exhibit 3, starting at page ending in Bates No. 8379 and through the page ending 8392, can you verify that that is the response that you submitted with supporting declarations to the October 2015 office action where the Examiner rejected the claims over the FDA label?

"Answer: Although I cannot verify the completeness and correctness of the entire span of pages that you indicated to me, based on the representation that you made earlier that this is an accurate representation of the file wrapper for this patent, I do believe this is the response to the office action.

"Question: By signing this document on behalf of Wilson Sonsini Goodrich & Rosati as attorneys for the

applicant, you were intending the Examiner to understand that the remarks were being submitted by yourself in that capacity; is that correct?

"Answer: That is correct.

"Question: And you understood when you signed this response to office action that you were under the duty of candor to the Patent Office, correct?

"Answer: Yes.

"Question: And you understood when you signed this November 24, 2015, response to office action that you were under a duty not to make false statements to the Patent Office, correct?

"Answer: Yes.

"Question: At the -- at the top of the paragraph, you state on page ending in 8385 that the label discloses part of the subject matter of the claims; do you see that?

"Answer: I see where the document says that.

"Question: And in the second full paragraph on page 8385 of your response to office action dated November 24, 2015, where you refer to the label disclosing part of the subject matter of the claims, the subject matter you're referring to is the disclosures in the label set out in the following sentences of the paragraph, correct?

"Answer: I believe that's correct.

"Question: Okay. And then after setting out what that subject matter is, you state that, 'Kannan states that the FDA obtained this information from V. Kannan and Matthew Kenney as they invented this subject matter'; do you see that?

"Answer: I see where the document says that.

"Question: Now, Mr. Kannan's declaration is in Exhibit 3 at Bates number ending in 8388 through 8390; do you see that?

"Answer: I see that.

"Question: And that is the Kannan declaration that you were referring to in the November 24, 2015, office action, correct?

"Answer: Yes.

"Question: Did you play a role in drafting that declaration?

"Answer: Yes.

"Question: You did not tell the Patent Office during prosecution of the '239 patent that Mr. Kannan's only contribution to the subject matter of the FDA label was with respect to refrigeration, did you?

"Answer: I do not recall such a statement.

"Question: The document starting on Bates No. 8403 in Exhibit 3 is the Examiner's summary of an interview

between yourself and the Examiner held on November 24, 2015, correct?

"Answer: The document is a record created by the Examiner based on the interview. Whether the Examiner's statements would be considered a summary is something I'm not willing to opine on.

"Question: Okay. If you look on the page ending in 8406.

"Answer: I'm looking at that page.

"Question: The Examiner states that prior to the interview, applicants sent two unexecuted declarations under 37 C.F.R. 1.30(a) by facsimile regarding the FDA Vasostrict reference cited in the final rejection mailed October 21, 2015; do you see that?

"Answer: I see where the document says that.

"Question: Okay. And then during this interview on the 24th of November 2015, the Examiner in her summary states that she recommended amending paragraph 7 to include a reference to all of the subject matter from the FDA reference relied upon in the rejection and an unequivocal statement that one or more joint inventors invented all of the subject matter relied upon.

"Do you see that ?

"Answer: I see where the document says that.

"Question: The summary goes on to say, this is

on page ending 8406 of Exhibit 3 that applicant's representative asserted that the inventor is responsible for all of the subject matter in the FDA reference and would be able to make this statement.

"Do you see that?

"Answer: I see where the document says that.

"Question: And the applicant's representative there is referring to you, right?

"Answer: I think the statement refers to me.

"Question: And so at this interview with the Examiner the day before you submitted your November 25th, 2015, response to office action, you told the Examiner that the named inventors were responsible for all of the subject matter in the FDA reference, right?

"Answer: I do not recall.

"Question: And after the November 24, 2015, interview between yourself and the Examiner, Mr. Kannan's draft declaration was amended to add the statement that he and Matthew Kenney invented the subject matter in paragraph 7 of the declaration, right?

"Answer: I believe that edit was made after the interview.

"Question: Let's take a look at the page of Exhibit 3 that begins -- that ends in 8417.

"Answer: I'm on the page 8417.

"Question: Okay. And if we look at the page ending in 8419, which is page 2 of the office action, you'll see a heading withdrawing rejections; do you see that?

"Answer: I see where the document says that.

"Question: And there the Examiner states that the declarations under 37 C.F.R. 1.130(a) filed November 24, 2015, are sufficient to overcome the rejection of claims 16 to 29 based upon FDA label for Vasostrict NPLU PTO '892 published April 2014; do you see that?

"Answer: I see where the document says that.

"Question: The Examiner states that the declaration by inventor Vinayagam Kannan includes an unequivocal statement that he and Matthew Kenney invented the subject matter disclosed in the FDA label and relied upon in the rejection and reasonable explanation for the presence of the FDA as an author of the prior art disclosure.

"Do you see that?

"Answer: I see where the document says that.

"Question: And then the Examiner states that, accordingly, the rejection of claims 16 to 29 under 35 U.S.C. 102(a)(1) as anticipated by or in the alternative under 35 U.S.C. 103 as obvious over the FDA label for Vasostrict is withdrawn; do you see that?

"Answer: I see where the document says that.

"Question: As of the date of the January 11, 2016 office action, you had successfully overcome the rejection of claims based on the declarations supporting that Mr. Kannan and Matthew Kenney invented the subject matter disclosed in the FDA label and relied upon in the Examiner's rejection, right?

"Answer: Page 8419 of the office action bears out the statement of withdrawal."

(End of videotaped deposition.)

THE COURT: Okay.

MR. HALES: One question on housekeeping, Your Honor. We had a number of arguments about the sword/shield issue with Mr. Kenesky. We understand the rulings on that and the testimony has been withdrawn reflective of that.

THE COURT: Wait, wait, wait. Let's be really precise.

MR. HALES: Yes.

THE COURT: There was a specific -- there was a specific question and answer objected to and I sustained the objection.

MR. HALES: Correct.

THE COURT: Is that what you are referring to or are you referring to something broader?

MR. HALES: Mr. Black had said at the time there were additional questions and answers they objected to. After you made that first ruling, we agreed with it, that we could apply that ruling to similar questions and we did that.

THE COURT: I didn't rule on it. I ruled -- I'm one who tries -- well, there was a specific objection to a specific question and I ruled on it.

I didn't articulate the full basis of my ruling. I sustained the objection under Rule 403, but I will add to the ruling.

I was informed by the next question, which was kind of a -- my recollection is the witness said in response to the questioning is, essentially, I don't accept you're telling for me or something like that.

I think he testified that he took umbrage with the questioner, essentially Mr. Lasky trying to testify. That's what the witness said. I was somewhat informed by that. But I didn't rule on any other questions and answers.

MR. HALES: All I was trying to do, Your Honor, is ask for the appropriate way to make an offer of proof, whether you want that now or as to the questions that were sustained.

THE COURT: There was only one question. That's what I'm saying. Before you start -- you've got to make an

offer of proof. I have not sustained the objection and maybe that could have been on my bad. I mean, things unravel at trial. Maybe I said something, but just in my mind, I was only ruling on the specific question.

MR. HALES: I think at the moment it happened, Your Honor, when that -- when the objection was sustained, I think what Mr. Black said, I'm going through memory obviously, was there are others that he believes we could work out. I agree with that and I did.

I'm not trying to put them in, Your Honor. I'm not trying to read them to you or present them to you. I just wanted to note the lines and pages that we were intending to present until Your Honor ruled against our ability to do so.

THE COURT: That's what I'm saying. I mean, I don't think it's fair, and, again, maybe I'm wrong, but in my mind, I didn't rule against you other than the specific question that was put before me.

So I have not ruled on the others. You're making an offer of proof for something that in my mind I have not precluded you from putting in at trial yet.

MR. HALES: I think, and maybe this will help. We had a series of questions that we had asked Mr. Kenesky where there was an instruction not answer based on privilege.

THE COURT: Okay.

MR. HALES: Your comments that day and as well as comments from the pretrial conference in January indicated that you didn't think it was appropriate for us to show you questions like that. Right. And our point -- so our point --

THE COURT: Your point is you think you can play at trial if you put a question to somebody and they refuse to answer. Based on privilege, you can put that in front of the fact-finder.

MR. HALES: For the purpose of ensuring that things that we were not allowed discovery of on the basis of privilege, whether right or not, right, assuming it was right, that they can't later argue in violation of the sword shield principle that, you know, inconsistent with the area that he couldn't get discovery of. So they may or may not do it. All I am saying is we could deal with it in the briefing or do you want to know what the page and line numbers were just to have it in the record?

THE COURT: Now, I --

MR. HALES: Apologies for lack of clarity.

THE COURT: You don't have to apologize. Usually, the stuff is 50/50 due to me and maybe more, so that's okay.

If they are going to argue that you didn't make

your case because you couldn't adduce at trial evidence of what the inventors said Kenesky and who played what role in drafting the affidavit, I mean, that's not going to go very far.

MR. HALES: I understand.

THE COURT: I mean, you've got a circumstantial case. They don't have to waive the privilege, but they didn't waive the privilege.

MR. HALES: Understood.

THE COURT: So go ahead and make your record.

MR. HALES: I mean, I just wanted to identify, and who knows if it will come up in the briefing or not, it can be dealt with. What we were intending to play were in addition from the deposition of Kenesky, lines 107, 10 to 14; lines 107 to 116, 24; lines 133, 3 through 8; 133, 14 to 18; 133, 25 to 134, 9. I should make that clear. 133, line 25 to 134, line 9. 136, line 6, to 137, line 20 and 152, line 3, to 153, line 11.

Now, you don't have those in the binder, obviously.

THE COURT: Well, I can make it part of the record.

MR. HALES: We can do that as well, Your Honor.

THE COURT: And we'll probably talk at the end of the day how to address this issue.

MR. HALES: Understood. I was just trying to preserve it.

THE COURT: Okay. All right. Next. Wait, Mr. Lasky, can I ask you something? Maybe you're not the right person, but since you offered the deposition, I notice you opened up that deposition with basically somebody taking note of who was present, including all the various lawyers. Did you put that in there?

MR. LASKY: We did not. They counter-designated that.

THE COURT: Okay. Mr. Black, why did you do that? I'm just curious.

MR. BLACK: I just wanted you to understand there were two people making the objections. I guess the objections were taken out, but one was from Wilson Sonsini and there was a lawyer for us as well.

THE COURT: All right. Thank you.

And then, Mr. Lasky, you asked some questions about post-AIA versus pre-AIA.

MR. LASKY: Yes.

THE COURT: What's the significance of that?

MR. LASKY: The significance is the law has changed now in terms of what the priority date is and what the rules on in materials of disqualifying prior art.

The rule under which they disqualified the

reference as prior art was introduced under the AIA and what that says is that a reference that is from one year -- less than one year before the filing date of the patent can be disqualified if you can prove that it was provided to -- it was disclosed by the inventors of the subject matter in that reference.

THE COURT: I see. That rule did not exist under the pre-AIA statute?

MR. LASKY: That's correct. Not in that form.

THE COURT: Got you. Thank you.

All right. Next?

MR. HALES: I'm told there are no exhibits to move in on that that were not already in.

THE COURT: I have another question. Are you all submitting a video for me?

MR. HALES: I don't think you have it yet. We can do that.

THE COURT: Are you doing that for all the depositions, Mr. Black?

MR. BLACK: I have to think about that, Your Honor. It's a little unfair. We had live witnesses here during the trial. Whatever impression they make, they make and you have video clips that are allowed to emphasize -- most of their case is video. It's not really fair for you to be able to review all the material and all the

depositions when you can't review the testimony from people here. I'm not sure. Maybe that's done sometimes.

THE COURT: I mean, you know, look, there's no suggestion, I'm not suggesting that what I'm about to say that you are breaking any rules or anything, but, you know, this was pretty important testimony. I mean, I don't know what this fellow does these days and maybe, you know, under a legal argument, he's not under your control, but he didn't testify live.

So, you know, why shouldn't I get to look at the video? I'm not sure I have to relook at it, but, you know, just --

MR. BLACK: I just -- I want to think about it, Your Honor, because it's unusual and --

THE COURT: It's unusual only because --

MR. BLACK: It's unusual to have the deposition clips submitted to the fact-finder of fact, whether the jury or the judge, because the live testimony is live. He just testified live in the courtroom just as if he were here. It puts more emphasis on that testimony that would otherwise be normal and I just want to not agree to it until I can think about it.

THE COURT: Okay. Thank you. All right. Next?

MR. LASKY: And just for the record, Your Honor, I will read in the time from Mr. Kenesky's deposition.

Defendants' time, 12 minutes, 9 seconds. Par's time, three minutes, 10 seconds, for a total time of 15 minutes and 19 seconds.

The defendants call by deposition designation Mr. Vandse. Mr. Vandse is a named inventor on the patents-in-suit and was deposed in his personal capacity.

Defendants' designations are relevant to the issue of obviousness and the criticality response to obviousness.

THE COURT: All right. Thank you.

MR. LASKY: To be clear, Your Honor, we're going to start with the deposition from the Eagle case and then Par has counter-designated some testimony from the Amneal case. There's no defendants' designations from that case.

THE COURT: All right. Thank you.

(The videotaped deposition of Sunil Vandse was played as follows.)

"Question: Could you please state your full name for the record?

"Answer: Sunil Vandse.

"Question: Based on studies that you performed and the conclusions you reached, to achieve the best combination of assay and impurities stability that you found, you would need to have a batch designed to have a pH 3.8 initially, correct?

"Answer: To the best of my recollection, that is correct.

"Question: And based on the studies you performed and the conclusions you reached, a batch that's designed to have a pH of 3.4 to 3.6 on release, but that subsequently drifts to a pH of 3.8, would not achieve the improvement in assay and impurities stability that you have found studies, correct?

"Answer: I do not recall having performed any such studies where the batch was made with 3.4 to 3.6 pH and then made to drift to 3.8 and then evaluated the stability profile.

"Question: So is it fair to say then that you cannot conclude based on your studies that you did and submitted to the Patent Office that a batch formulated to have an initial pH of 3.4 to 3.6 that drifted to 3.8 would have improved stability as compared to a formulation that did not drift?

"Answer: I have not done any study to simulate the condition that you're describing, so I have no basis to say it's better or worse.

"Question: How does one determine what the best combination of assay and impurity results is?

"Answer: Higher the assay and lower the impurity at a particular given pH.

"Question: But which -- which gets precedence, lower impurity or higher assay?

"Answer: Both are important.

"Question: Okay. Well, the -- if you look at the assay results and compare them to the impurity results, they give different conclusions as to which is the most stable among these formulations you tested, right?

"Answer: (Reviewing.) Not really. If you look at the best combination, 3.7 to 3.9 range are the best combination.

"Question: In making conclusions comparing formulations with different pHs, is it important to account for differences in starting levels of impurities?

"Answer: If the objective was to pick a formulation which would yield lowest impurity at the end of shelf life, then I would look at what is at the end of shelf life or at the end of the study period rather than the beginning.

"Question: As between two formulations of Vasostrict that meet the specifications for the same approved shelf life, are you aware of any advantage to having less vasopressin impurities?

"Answer: Less impurities means it is less side effect or safer for the patient.

"Question: Are you aware of any data showing

any safety advantage between the reformulated version of Vasostrict as compared to the original formulation of Vasostrict?

"Answer: I am not aware of any such studies.

"Question: Do you think you developed such technology, that is, a formulation of vasopressin, chlorobutanol, water and acetic acid targeted to pH 3.4 to 3.6 that subsequently drifts to 3.8?

"Answer: No, I did not.

"Question: Can you please get in front of you, I believe it is your second declaration, which I believe is Vandse 12.

"Answer: Yes, I have that.

"Question: Okay. And do you recall that Mr. Lasky was asking you about the absence of data points in Figure three for several of the point, 3.5, 3.7 and 3.8?

"Answer: Yes, I do.

"Question: Okay. Now, if you go to any -- and I think you looked to see whether there was -- I think you testified there's no percentage assay decrease that's provided in a table in the declaration.

"Do you recall that?

"Answer: Yes, I recall that.

"Question: Okay. If you go to Appendix 2, is there information from which one would be able to determine

the percentage change in assay for those data points?

"Answer: Yes, there is information.

"Question: And where is that information?

"Answer: In Appendix 2, you will find the assay at -- for pH 3.5 at week zero and similar number for pH 3.5 at week four.

"Question: And is that also true for the other data points that Mr. Lasky mentioned?

"Answer: That's right.

"Question: 3.7, 3.8?

"Answer. That's right.

"Question: And for those various data points, did the assay -- did the assay change increase or decrease?

"Answer. The assay increased.

"Question: So if that were to be plotted in Figure three, would it be -- where would those data plots be as compared to the X axis?

"Answer: It will be below zero. So it will be in the negative region, which cannot be shown in this plot.

"Question: Okay. And so the information about the percentage change in assay value for those data points was included in your declaration and available to the Examiner; is that right?

"Answer: That is correct.

"Question: And what did the team do to improve

the stability of vasopressin formulations?

"Answer: The original vasopressin formulation had a limited shelf life of 12 months at room temperature, and in order to improve the shelf life, we screened more than 50 different combinations of buffers, of buffer concentrations, stabilizers, pH, various processing conditions, and like overhead head space, oxygen content, and various parameters were screened, and through methodical screening, we eliminated different parameters which had no impact on the stability both with respect to the assay and impurities, and narrowed down through experimentation and scientific reduction to a few parameters and then eventually focused on that buffer as well as a specific pH range which had impact on the vasopressin assay as well as total impurities and controlled that and optimized it in such a way that the shelf life of 18 months was achieved at room temperature.

"Question: So this is Exhibit 11 to your deposition. I would like you to find the January 2016 declaration that you provided to the Patent Office which is within that exhibit.

"Answer: Yes, I have that.

"Question: Do you see in paragraph 14 the second sentence says, the most favorable results were obtained at pH 3.8, which provided excellent vasopressin

stability at both temperatures tested?

"What is the pH of the commercial reformulated Vasostrict product?

"Answer: ph 3.8.

"Question: It is Exhibit 12 to your deposition. Do you have that, Mr. Vandse?

"Answer: Yes, I have that.

"Question: Could I have you please look at pages 12 and 13 of the technical report F.R.D.-15-012.

"Answer: Yes, I have that.

"Question: What do these two pages of your technical report for reformulated Vasostrict describe?

"Answer: Page 12 describes the experiments conducted to evaluate effect of pH on the stability of vasopressin. It describes that 11 batches were manufactured from pH 3.5 to 4.5 and they were subject to stability at 40 degrees Centigrade.

And page 13 of the report summarizes the results of these experiments over a period of four months where the samples were tested at one month interval and stored at 40 degrees Centigrade for four months.

"Question: Now, back on page 12, there is a statement near the bottom of the paragraph that states, the most stable region of pH for total impurities is from 3.7 to 3.9. Taking this into consideration, pH 3.8 is the desired

target pH for vasopressin solutions.

"Is the statement that I just read from the technical report consistent with your team's conclusions concerning the optimal pH for reformulated Vasostrict?

"Answer: Yes, it is consistent. In both cases we have said that pH 3.8 is the desired target pH for vasopressin solution, and pH 3.7 to 3.9 is most stable range.

"Question: Are the conclusions that we just looked at from the technical report and from the January 2016 Vandse declaration consistent with each other?

"Answer: Yes, they are.

"Question: Now, after your team obtained this information, what did the team do with the information?

"Answer: Once this information was available, we had decided -- our recommendation of the team was that pH 3.8 acetic buffer at ten millimolar is a prototype formulation which we can take forward to the registration stage. That was the next step.

"So we recommended that to the management, and management agreed with our recommendation, and then we proceeded to manufacture the registration batches and conduct formal GMP stability studies. Once that was concluded, together with the regulatory affairs department, we submitted an application to FDA for approval.

"Question: One last question, which is at any time during the prosecution of any of your patents relating to vasopressin, did you take any steps whatsoever that were intended to mislead the Patent and Trademark Office?

"Answer: No. No, I did not do any such steps, I did not take any steps to mislead the Patent Office."

(End of videotaped deposition.)

MR. RHOAD: Your Honor, following Dr. Vandse's testimony, plaintiffs move to enter three exhibits into evidence. It's DTX-0069, DTX-1161, and DTX-1162.

THE COURT: All right. Thank you.

MR. LASKY: No objection.

THE COURT: And there's no objection, so they are admitted.

(DTX-0069, DTX-1161, and DTX-1162 were admitted into evidence.)

MR. LASKY: Your Honor, for the record, from the Eagle transcript, the designations were two minutes, 32 for defendants, and four minutes, 40 for Par, and from the Amneal transcript that was all Par, seven minutes and 50 seconds.

And defendants now call the last deposition witness. The witness is Suketu Sanghvi.

Suketu Sanghvi is a named inventor on the asserted patents. He was deposed in his personal capacity

and also pursuant to Federal Rule of Civil Procedure 30(b)(6) for Par, and his testimony, at least defendants' designations relevant to again obviousness and the criticality rebuttal to that.

THE COURT: All right. Thank you.

(The videotaped deposition of Suketu Sanghvi was blade as follows.)

"Question: Could you please state your fall name and address for the record?

"Answer: My name is Suketu Sanghvi, and I live at 1 Hancock Drive, Kendall Park, New Jersey.

"Question: What is your current role at Par?

"Answer: I'm senior vice president for research and development.

"Question: Currently marketed formulation of Vasostrict, do you understand that's stated to have a pH of 3.8, right?

"Answer: Correct.

"Question: So what does that pH of 3.8 refer to?

"Answer: My understanding is the pH of 3.8 refers to the pH of the solution.

"Question: Which solution?

"Answer: The vasopressin that's currently on the market.

"Question: Okay. When, like at all times through its shelf life initially or at some other time?

"Answer: At the time of manufacturing.

"Question: Okay. Reformulating Vasostrict from the original to the current formulations did not lead to Par seeking or obtaining a lower total impurity specification at release, correct?

"Answer: The specifications that FDA approved is the same for total impurities.

"Question: Okay. And reformulating Vasostrict from the original to the current formulation did not lead to Par seeking or obtaining a lower total impurity specification for shelf life, correct?

"Answer: As I mentioned, the specifications for total impurities are the same.

"Question: The question is between the original and the reformulated Vasostrict, the specification for assay at release did not change?

"Answer: No, the numbers are identical for release, but they are different for the shelf life.

"Question: So I'm actually asking you if you're aware of any such data.

"Are you aware of any data whatsoever showing the benefit of having a pH that starts within the range of 3.4 to 3.6 at release, but then goes up to 3.8 during the

shelf life?

"Answer: I don't recall such data.

"Question. Can you conclude from this one result, the 3.8 at 18 months, that other batches of original Vasostrict are likely to also raise to 3.8 during the shelf life?

"Answer: No. I need to look at the data to see if they behave the same or different.

"Question: What in your view is the advantage of formulating a vasopressin product at pH 3.8 as compared to 3.6?

"Answer: It's my understanding the product has -- is more stable at pH 3.8.

"Question: What do you mean by more stable, under what sense?

"Answer: More stable in the sense there's less degradation product.

"Question: When Par concluded that 3.8 was the optimal stability for vasopressin, were you surprised?

"Answer: It was not something we expected, so based on the data, we came to that conclusion.

"Question: Well, you said it wasn't something that you expected, and so my question is, was there anything that you did expect to come out of the data when doing the pH stability study?

"Answer: Based on the literature search, we had seen some articles that suggested lower pH to be more stable and we found it to be the other way around."

(End of videotaped deposition.)

MR. LASKY: Your Honor, for the record, the time from the initial transcript that was the Eagle case, defendants' designations, two minutes flat. Par designations, one minute, 19 seconds. And from the Amneal transcript, 41 seconds for plaintiffs.

THE COURT: Thank you.

MR. HALES: With that, Your Honor, Eagle rests their case.

THE COURT: Thank you.

MR. HALES: Amneal as well. Defendants rest.

THE COURT: Thank you very much.

MR. BLACK: Thank you, Your Honor. I have a brief motion under Rule 52(c).

THE COURT: All right.

MR. BLACK: With respect to defenses that were not presented that are in the pretrial order in particular.

So there were Section 112 defenses in the pretrial order which were not presented at trial and I did not hear an anticipation opinion and we'd move for judgment under Rule 52(c) on 112 and anticipation defense.

MS. WACKER: We oppose on the 102 argument. There was evidence that came in that established Original Vasostrict is substantially the same as our products accused of in infringement. There is case law we can rely on.

THE COURT: Let's deal with the 112. Did you dispute the 112?

MS. WACKER: No.

THE COURT: I hear you. I think it's wise to do what you did, so the 112 arguments are dispensed with.

As far as the anticipation?

MR. BLACK: There really was no -- for anticipation, you have to identify a specific single piece of prior art which meets all of the elements of the claim, and in this case, the claims require pH of 3.7 and 3.9 at the same time as all the various impurity limitations, and there are eight permutations of that in the claims and they have not identified a single lot of Vasostrict, single vial of Vasostrict which fell within the scope of any of the claims let alone any of the dependent claims. It was an anticipation case.

To the extent we heard, it was kind of a fly-by anticipation or obviousness and they really presented an obviousness case and we don't move on that. So on anticipation, they did not identify any specific piece of prior art that meets all limitations of all of the claims,

in particular, the dependent claims and the result of those discussions.

THE COURT: Ms. Wacker?

MS. WACKER: We disagree. The prior art, the original Vasostrict as a whole. The properties of that product were available in the art. There's case law stating that.

So then as they're asserting, our product infringes the claims and our product is a copy of the RLD of original Vasostrict. So under the case law, those products are substantially similar, we think the evidence shows we can anticipate those claims.

MR. BLACK: So, two points. First, the standard for anticipation. Then I want to address this RLD issue. She said it's the same as the RLD.

THE COURT: Okay.

MR. BLACK: I misheard her.

THE COURT: No, no. She did.

MR. BLACK: So anticipation requires a piece of prior art. Now, what could that be?

The label for original Vasostrict they assert, but that does not, the label does not have in it any discussion about impurities, so as a matter of law, it doesn't qualify for anticipation.

THE COURT: All right.

MR. BLACK: A vial of original Vasostrict sold more than one year before the priority date could constitute on-sale bar, but they didn't identify any vial of the product, they didn't produce any evidence of any vial of the product that has actually been sold before the priority date and which had the requisite pH and impurity limitation let alone all the impurity limitations in the dependent claim.

They cannot come --

THE COURT: Let's stop there.

MR. BLACK: Yes.

THE COURT: Do you dispute that?

MS. WACKER: I do dispute that. We have events in the case, the original Vasostrict product as a whole were sold starting in 2014 and the impurity properties of that product which was sold could have been measured by an expert. We also presented evidence of impurities with respect to representative batches, first of all, of their product.

THE COURT: But did you present any evidence of -- okay. What did you present in the way of representative impurities?

MS. WACKER: So a couple of different things.

So we presented impurities with respect to when Par submitted the NDA, they submitted registration batches, similar to the batches that we've submitted in our ANDA that

they are relying on for infringement. So the properties of those products are meant to be representative of the products that they are still selling.

This idea that you can't test every single product you're selling commercially, so you tell the FDA this stability data and this test data is representative of the product that we're selling.

THE COURT: Did you have a piece of evidence that showed what the impurities were prior to, what is it, February 2017. Right?

MS. WACKER: Yes.

THE COURT: What was the piece of evidence?

MS. WACKER: That was the registration document.

THE COURT: The registration batches? So they disclosed in the registration batches you're saying --

MS. WACKER: Certain impurity information.

THE COURT: I want to make sure, and it matches the claims, the impurities?

MS. WACKER: Yes.

THE COURT: All right.

MS. WACKER: And we also disclosed -- there was evidence of batches that were sold commercially that had stability data.

THE COURT: Right.

MS. WACKER: So not every batch that is sold

commercially has stability data. The companies aren't required to have stability data for every single batch. So there are some batches that we presented evidence on impurities for that we know were sold as well based on the sales record.

THE COURT: All right.

MR. BLACK: Registration batches were never sold.

THE COURT: Do they have to be sold?

MR. BLACK: To be an on-sale bar, they do.

THE COURT: But -- I have to say, I will be honest with you. I get confused with the on-sale bar.

So --

MR. BLACK: So, first of all, any information about the registration batches was private and not published, so it can't anticipate. The information about. There's a difference between they have printed publication and something that was on sale. The information about the registration batch --

THE COURT: So let's play this out.

MR. BLACK: Yes.

THE COURT: Sorry. So I guess, and it makes sense to me that if it's confidential information, it's not in the prior art. I get that. But it's undisputed that the original Vasostrict was prior art. Right?

MR. BLACK: Yes.

THE COURT: All right. And your thing is, as I understand it, but they have not established that the POSA would have known prior to February 2017 that the original Vasostrict had the claimed impurities. Right?

MR. BLACK: Yes. It's a little -- it's not actually so much a POSA question. If I might, Your Honor, I have to expand a little bit to answer the question.

THE COURT: Sure.

MR. BLACK: So there are different types of prior art under 102 that can anticipate. Most cases are about a document and you can't combine documents for anticipation.

THE COURT: Right.

MR. BLACK: So you've got to find it -- every element in a single document. They are not running that test. They don't have that.

THE COURT: All right.

MR. BLACK: They discussed some documents from Par, but those documents are not in the prior art, as you noticed.

THE COURT: Right.

MR. BLACK: Documents. I'm going to get to it.

THE COURT: The documents.

MR. BLACK: The thing, you can also under

102(a), a real world thing that is sold.

THE COURT: It has to be sold?

MR. BLACK: It has to be sold.

THE COURT: The real world thing, I want to make sure.

MR. BLACK: Sold or offered for sale, but sold in this case.

THE COURT: Okay.

MR. BLACK: Has to be actually sold.

THE COURT: Right.

MR. BLACK: With all the properties of the claim.

THE COURT: Right.

MR. BLACK: At the time that it's sold. That they have not proved with respect --

THE COURT: I want to make sure on the law. You are saying that it has to be at the time it was sold, the thing, not during the shelf life.

MR. BLACK: If it was during the shelf life, but within the -- but outside the one year grace period, it would qualify because it could be used then, right, after the sale. At the time of sale or later, yes.

THE COURT: Okay. At the time of sale or later, all prior to the priority date that the product that is offered as prior art must have had the claimed impurities?

MR. BLACK: Right.

THE COURT: Okay.

MR. BLACK: And for the dependent claims to anticipate, they have to show each one of those little things.

THE COURT: If I was boiling it down, I would say, therefore, the burden would be on Eagle and Amneal to show that a prior -- that an original version of Vasostrict sold no earlier than February 2016?

MR. BLACK: Correct.

THE COURT: At some time between February 2016 and February 2017, it had the claimed impurities.

MR. BLACK: No. It would have to have the claimed impurities before February of 2016. The piece of prior art has to infringe the claim. The product has to infringe the claim before February 2016, so they have to identify a vial by clear and convincing evidence.

By clear and convincing evidence, they have to show that a vial was sold or in use before February 2016 --

THE COURT: Okay.

MR. BLACK: -- that had a pH of 3.7 to 3.9.

THE COURT: At some point before February --

MR. BLACK: And gly9 and all the other limitations.

THE COURT: Okay.

MR. BLACK: And they did not meet their burden.

THE COURT: Let me make sure they agree that's the test.

MS. WACKER: So the test is you don't have -- so the product was on sale, I think it has been agreed it was on sale starting in November of 2014.

THE COURT: Right.

MS. WACKER: So between November of 2014 and February 2016, lots of original Vasotrict are being sold.

THE COURT: Correct.

MS. WACKER: Okay. And so the test is, would that product that's being sold have anticipated the claims.

THE COURT: I think you have agreement on that.

MS. WACKER: I think we agree on that part. The part we don't agree on is a person of ordinary skill in the art can look at the, what is representative of the product that is being sold.

THE COURT: Isn't that an inherency argument essentially?

MS. WACKER: It's not necessarily inherency.

THE COURT: No?

MS. WACKER: We have evidence of representative batches and batches that were put on stability that show how that product was made and the drift that it had and the pH

and impurities that it had, so that evidence that we have put into the case establishes what all of the products that were being sold on the market would be.

And the reason the law is that way is because when products are sold, people can go out and test it, right, so it's back in time, so you can't go back in time and try and test it now. So it would be impossible for us to go get vials at the time they were sold and test the impurities and test the pH and know what it is today and that's why you could look at what is representative of what was being sold.

We're happy to brief it, Your Honor.

MR. BLACK: The law is that they don't, they don't -- they have to show evidence by clear and convincing evidence that there was a vial that was on sale or in use which had all the properties of each claim with dependencies before the priority date and they didn't produce that evidence. They did not meet the burden for anticipation.

THE COURT: So I just want to get a couple points of clarity.

So I'm familiar with what I will call an inherency argument, so that, in other words, I'm familiar with an argument that if applied in this case would be that the challenger can show that the original Vasostrict was on the market in 2014 and February of 2015, and second is that

a POSA would know because it was inherent in the property of original Vasostrict that it had the claimed impurities, but I want to make sure you are not making that argument. Correct?

MS. WACKER: I think in part. I want --

THE COURT: I don't know why it's not real easy. Either you are or you aren't.

MS. WACKER: Sort of. We're not saying that every single batch of original Vasostrict had a pH of between 3.7 and 3.9, because what was representative of the batch is some did, some didn't.

THE COURT: So it's not inherent then?

MS. WACKER: It is inherent for some of the batches. Does that make sense?

MR. BLACK: That's not inherency.

MS. WACKER: It is an inherent property. The stability -- the impurities and pH are inherent properties.

THE COURT: I don't understand how something can be an inherent property. I mean, I thought the whole notion of inherent was it's always going to be found there. That's why we call it inherent. I think if you look up the dictionary definition, it probably says something.

MR. BLACK: That's correct, Your Honor. That's why you're exactly right, the issue comes in play in

anticipation. If there's some element that can't be shown, but it must be there, then you can assume it was there. However, here, the evidence is that pH is usually 3.4 to 3.6.

THE COURT: I think that's what we just heard. That's why I'm having a hard time. Are you or are you not arguing inherency?

MS. WACKER: So we are arguing for certain batches, they were released at pH of 3.7 that drifted into 3.7-3.9, and they have the inherency properties.

MR. BLACK: There's no evidence of that. They have to show a specific batch. They had their opportunity. They didn't do it. There is none. There is no such batch.

THE COURT: I am perplexed, because essentially if the argument is inherently some original Vasostrict drifts into infringement, I don't know how you would square that with your noninfringement argument.

MS. WACKER: And I think that's the point we're making, that the claims are read as broadly as they're saying with any drift and the pH specification as we showed for the original Vasostrict actually was much broader, so they manufactured it between -- the stability was between 2.5 and 4.5.

So as the original product was made, it was made

at higher pH's of 3.7 because it was allowed to be. It was allowed to also be in a much broader stability specification for shelf life whereas Eagle's product is much narrower and at a lower pH.

MR. BLACK: They have to show a thing in the world that was sold the year before the priority date, which had both the pH of 3.7 to 3.9, and an impurity level as required in the claims. They just didn't -- they didn't do it.

MS. WACKER: I've also been informed by my colleague that the correct date is actually February of 2017 post-AIA.

MR. BLACK: I may be wrong.

THE COURT: That's what I thought originally. I thought I got corrected by everybody, so I backed off.

MR. BLACK: You know what, I've been doing this long enough. This is post-AIA, so it's before the priority date, February 2017. But the rest of the argument stands.

There's no evidence in the case, Your Honor, that there were vials sold that actually had those properties. Clearly, pH is not inherent. Clearly, the impurities are not inherent, and therefore they can't rely on simply the fact of a sale of vials from a batch. They have to show that there was a batch and that it happened.

THE COURT: Yes.

MR. BLACK: And it's their burden and they have to do it by clear and convincing evidence. There was no evidence on it let alone anything clear and convincing in Dr. Park's testimony, who is the only one who conceivably testified on that issue. He glided right by the impurities.

THE COURT: Let me ask Ms. Wacker a question.

So the premise it seems to me, kind of all of these arguments that you are making related to this issue, is that your product is the same thing as original Vasostrict.

MS. WACKER: We use original Vasostrict -- we are the same with the exception we have a narrower pH specification.

THE COURT: But what I'm getting at is that, what do you want to call it? Put aside RLD. I'm wondering whether it would have to be the same for the RLD. You're saying that it's a piece of prior art and I'm not sure that's the same question, is it the RLD.

And it seems to me you're saying that we can be -- this piece of prior art anticipates our product, right, because we've established that they're sufficiently similar that they are going to behave in the exact same way.

MS. WACKER: And I disagree they behave in the exact same way. However --

THE COURT: Well, they're going to behave the exact same way with respect to the claim limitation.

MS. WACKER: I don't agree with that.

THE COURT: How do you have an anticipatory reference?

MS. WACKER: The anticipation articles comes in that if these huge products which Par is alleging will inherently drift into 3.7 to 3.9 range, they're saying our product, even though we have the spec, we've narrowed it, we're below the range, we have a new manufacturing process. They are saying it's still going to drift up.

If that is true, then original Vasostrict would also have been doing the same thing based on the evidence relating to that.

THE COURT: Then it's also true that that is the logic I'm getting. This unstated premise of that argument, is that these two products are identical or at least you would have to say you can establish that the limitation at issue can only be changed by characteristics that are -- that both the original Vasostrict and your product have.

MS. WACKER: And I would not -- we have a better specification lower than a pH. But if our products --

THE COURT: But if they are not identical then, don't you have to establish that in all respects that could affect the limitations of the claims, they're identical?

MS. WACKER: I don't think you have to establish that as identical. They're substantially the same. And so if we're showing that our accused products, and so I think the test, it goes to what they're accusing of infringement. So because they are accusing our product of infringement, which has a narrower spec and is lower than the pH, their product, which has a broader spec and was released at a higher ph, would have inherently invalidated the claim if our product is also found to infringe. So our product has a narrower spec, lower pH.

THE COURT: But their product might have properties that are different than your properties that might make them drift differently. Right? I mean, the premise of your drift argument, as I understand it, is that, well, our property, our two products are basically the same thing, so they are going to drift exactly the same way.

MS. WACKER: I don't think that's true.

THE COURT: Then maybe you should clarify it for me. This is an example, and I just put it out there, is they -- and clients ought to do this. A judge, and especially somebody like me, I only have so much brain capacity and it's not as much as you all would like, it's not as much as I would like. So I work hard, but I am limited, and I'm just human.

And it just strikes me. You know, it's funny. You have some other arguments, and we're stuck on this, but we're going to be stuck on it, because if you want to make -- and, you know, it could be me and I'm going to try to read and learn, but, boy, you've got some other arguments that clearly, you know, I get, and we can talk about the merits of.

So I'm still hung up on how you make this comparison between original Vasostrict and your product, and you say, hey, original anticipates our product because -- and because basically they function in the same way in terms of drift.

And what I'm thinking is, well, then you've got to preclude all of the other characteristics that original Vasostrict has that your product doesn't as being determinative of drift. And I don't know. I'm not sitting here today going, oh, yes, these products, they should behave exactly the same when it comes to drift.

So tell me how you've put on evidence that establishes that or tell me why I've got the wrong question.

MS. WACKER: I will try to explain it. Our product has narrower pH.

THE COURT: Yes.

MS. WACKER: Narrower pH specifications.

THE COURT: I get that.

MS. WACKER: Okay. And Par's product, broader pH and evidence that they have pH results that are in higher, at higher levels than in our product.

THE COURT: Their pH meets stability results.

MS. WACKER: And release.

THE COURT: And release results.

MS. WACKER: They have a release of 3.7 for their product. Okay.

THE COURT: They had a broader release specification.

MS. WACKER: Correct. So we have evidence of Par's product that is higher pH than ours.

THE COURT: Okay.

MS. WACKER: And the broader pH specification.

THE COURT: All right.

MS. WACKER: We have evidence that their product also satisfied the impurity limitations of the claims, and so if our product with a lower pH is being accused of being able to drift up, their product, which has a broader pH and higher pH, would also drift. It's already there.

THE COURT: What affects drift? What affects the degree of drift?

MS. WACKER: Their product already starts at 3.7-3.9.

THE COURT: They might have other things. They

might have buffers or excipients, something, right, that means their product doesn't drift but your does.

MS. WACKER: All of the inactive ingredients are the same. And so, and I asked for --

THE COURT: Maybe you just answered the question. Is it undisputed that other than the pH range, these are, these two products are exactly alike?

MS. WACKER: No, because I think the manufacturing processes --

THE COURT: Maybe the manufacturing process could affect drift. In fact, didn't you optimize your practice to minimize drift?

MS. WACKER: I would agree that the manufacturing process does affect drift.

THE COURT: Okay. So are the manufacturing processes for the original Vasostrict and your accused product exactly the same?

MS. WACKER: They are not.

THE COURT: So then why am I in anticipation?

MS. WACKER: Because if our product, which has a narrower manufacturing process, right, of more --

THE COURT: I don't know anything about their manufacturing process. Have you established that your manufacturing process is narrower than theirs?

MS. WACKER: We've established that the pH

results of our manufacturing process are narrower and lower than their product.

THE COURT: Over time?

MS. WACKER: Yes. We have stability testing for their product and the release testing, so our specs are narrower.

THE COURT: I'm going to deny the motion. Go ahead and make your argument. I would think twice about it. I really would.

MR. BLACK: Thank you, Your Honor.

THE COURT: Because remember your burden. It's clear and convincing.

The motion is denied. What's next?

MR. BLACK: We're ready to put on our rebuttal case. Maybe this would be a good time to take a short break?

THE COURT: I think it's a good idea. What do you need?

MR. BLACK: Ten minutes would be fine.

THE COURT: Okay. Thank you.

(Short recess taken.)

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(Proceedings resumed after the short recess.)

THE COURT: All right. Please be seated. Before you get started -- well, maybe go ahead.

MS. WACKER: I just wanted to let Your Honor know we consulted with Amneal and with our clients and in order to streamline moving forward, we're willing to drop 102.

THE COURT: Anticipation?

MS. WACKER: Yes.

THE COURT: Well, that's a good thing because I was going to come out and grant it. I think it's a wise decision. I thought about it and I was going to grant it. But I don't have to worry about that. Perfect. You're withdrawing it. We're good.

And just to be clear, that means that you are abandoning the defense of anticipation over original Vasostrict with the prescribing information with respect to both the asserted claims of the asserted patent. Right?

MS. WACKER: That's correct, Your Honor.

MR. BLACK: All right. That's perfect. Thank you.

MR. RHOAD: So, Your Honor at this time we would call Dr. Vinayagam Kannan.

THE COURT: Very good.

MR. RHOAD: I believe binders have been handed up.

THE COURT: They have. Thank you.

... VINAYAGAM KANNAN, having been duly

sworn/affirmed as a witness, was examined and testified as follows...

DIRECT EXAMINATION

BY MR. RHOAD:

Q. Good morning, Dr. Kannan.

A. Good morning.

Q. Can you please tell us your, about your educational background?

A. I have a Bachelor's in pharmacy, a Master's in pharmaceutics and B.S. in pharmaceutical sciences.

Q. And when and where did you get your Ph.D.?

A. I got my Ph.D. in 2010 from the University of Tennessee Science Center in Memphis.

Q. Where are you currently employed?

A. I'm currently employed with Vertice Pharma.

Q. If you can maybe pull the mic a little closer so the rest of us can hear that. And is Vertice Pharma associated in any way with Par?

A. Not that I know of.

Q. But you used to work for Par; right?

A. I used to work for Par.

Q. Approximately when did you leave Par?

A. I left around May 2018.

Q. Now, the Court has already heard some of testimony that you have provided in this case at your deposition that

was played by videotape here, either yesterday or the day before and heard some about the projects that you worked on relating to Vasostrict, but I would like to go back and talk about some of the work you did.

Now, one of the projects that was mentioned that you worked on related to the dilution of Vasostrict in dextrose. Can you tell us about what that work involved and what your role in it was?

A. Yes. That work involved evaluating compatibility of vasopressin drug product when it is diluted with five percent dextrose solution. That involved also a study that evaluates how long that diluted solution can be stored.

THE COURT: I'm sorry. Sorry. We had a technical issue. Mr. Rhoad?

MR. RHOAD: Your Honor, with the Court's indulgence, I might ask the last question for context.

THE COURT: That would be fine. Thank you.

BY MR. RHOAD:

Q. So as I mentioned, Dr. Kannan, one of the projects that had been alluded to during the course of the videotape of your testimony earlier was a project relating to the dilution of Vasostrict in dextrose, and can you explain for us what that project was and what your role in the work you did on that relating to that?

A. Yes. The project was related to evaluating

compatibility of vasopressin drug product when it is diluted with five percent dextrose. My role was initially making an adjustment and trying to troubleshoot an issue that they were observing at that time. And when the vasopressin product was diluted with five percent dextrose, they were seeing a decline in potency, so I performed an adjustment with regard to troubleshooting that and later there was a study conducted evaluating compatibility and making the accommodation to watch to be included in the label.

Q. And did any of the work you did relate to the refrigeration of the diluted, of the vasopressin diluted in the dextrose?

A. Yes. As I mentioned earlier, the study was evaluation, evaluating under room temperature and refrigerated temperature.

Q. The Court also heard a little bit of testimony that you were involved in further project relating to refrigerated storage and shelf life of Vasostrict. And what prompted that work and what was your role in that work?

A. When Vasostrict was originally approved, it was approved with the shelf life of 12 months at room temperature. We discussed that as a team and decided to evaluate our refrigerated data for that product and see if we can get extended shelf life.

My work involved with my co-worker, Matt Kenney,

evaluating the data, performing analysis and making recommendations on what the shelf life would be at refrigerated storage and also supporting all the documentation prepared for regulatory filing.

Q. **Now, was Par successful in obtaining a longer shelf life for Vasostrict based on refrigerated storage and the work you did?**

A. **Yes. Par was successful in obtaining 24-month shelf life for refrigerated storage conditions.**

Q. **Now, you also did work on the reformulated version of Vasostrict; is that right?**

A. **That is right.**

Q. **And what prompted that work?**

A. **As I testified earlier, the original Vasostrict approval for room temperature was only for 12 months, so we discussed that as a team and desired to conduct additional studies to evaluate the stability of vasopressin and different formulations, so we were trying to see if we can get an extended shelf life that is more than 12 months.**

Q. **Now, were your efforts to develop a reformulated Vasostrict product successful?**

A. **Yes. The reformulated product was eventually approved by the FDA.**

Q. **Okay. So let's talk about some of the declarations that you signed in connection with the case that have been**

challenged here in Court. Did Par ever pursue patent protection relating to refrigerated storage of vasopressin?

A. Yes.

Q. And during the prosecution of that patent application, did you sign a declaration relating to that work that was submitted to the Patent Office?

A. Yes, I did.

Q. Okay. You have a binder of documents in front of you, hopefully. If you could look at PTX-329 and we'll pull it up on the screen.

And is this a declaration that you signed?

A. Yes.

Q. And when did you sign it?

A. It was signed on 24th November 2015.

Q. Okay. And at the time you signed it, did you believe that the statements you made in this declaration were true?

A. Yes.

Q. Now, you understand that the declaration was submitted in response to an, I will call it an office action from the Patent Office dated October 21, 2015?

A. That is correct.

Q. And it says that at paragraph 4?

A. Yes.

Q. Okay. Now, if you would, please turn to paragraph 6 of your declaration. And there, you say that you jointly

invented the subject matter of the currently pending patent claims; is that right?

A. **That is right.**

Q. **Okay. So let's take a look then at what those currently pending patent claims were. So if we could turn, if you would, please, to PTX-372. And, in particular, turn to page 3.**

A. **Yes.**

Q. **Okay. And if we could take a look at claim 16 which is on that page.**

To your understanding, did you, in fact, jointly invent the subject matter recited in this claim?

A. **Yes.**

Q. **And which part of the claim, if any, did you, did your work contribute to in particular?**

A. **My contribution was related to storing the unit dosage form.**

Q. **When you signed your declaration stating that you invented the subject matter of the claim, what did you understand the subject matter of this claim to mean?**

A. **My understanding on subject matter is that storing the unit dosage at 2 to 8 C at a combination of the items mentioned in the paragraph 16.**

Q. **When you signed your declaration, did you intend to convey that you had invented each individual element that's**

recited in this particular patent claim?

A. No, I did not.

Q. And did you intend to convey, for example, that you had invented administering vasopressin to a patient who was hypotensive?

A. No, I did not.

Q. Why not?

A. Because it's known a drug and it had been used for many years.

Q. All right. Let's turn back now, if you would, to your declaration, which was PTX-329.

A. Yes.

Q. Let's take a look now at paragraph 7. And did you believe that the statements you made in this paragraph were true?

A. Yes, I did.

Q. And do you see that in this paragraph, it identifies a number of statements from the label for Vasostrict?

A. Yes.

Q. And did any of the statements that are cited here from the label relate to the work you did on Vasostrict?

A. Yes. Where it states, the label, refrigeration of the diluted vasopressin in product for 24 hours, that came out of my contribution.

Q. Now, if you take a look at the last sentence in this

paragraph, it says that the FDA obtained this information from you as, and that you invented this subject matter.

Do you see that?

A. **I see that.**

Q. **And what did you understand this subject matter to be referring to?**

A. **The subject matter is referring to refrigeration of diluted vasopressin for up to 24 hours as a combination of all of the items stated in paragraph 7.**

Q. **Now, did you intend to convey to the Examiner that you had invented each individual item from the label that is recited here in this paragraph?**

A. **No, I did not.**

Q. **And, for example, did you intend to convey to the Examiner that you had invented the use of vasopressin to increase blood pressure in adults with vasodilatory shock?**

A. **No, I did not.**

Q. **Now, throughout the declaration, it refers to the capital "L" Label for Vasostrict. Were there, in fact, more than one FDA approved label for Vasostrict?**

A. **Yes. At that time, there were three FDA approved labels for that.**

Q. **And at the time you signed the declaration, what label did you have in your mind?**

A. **In my mind, I was thinking about the more recent label**

that was refrigeration.

Q. And why did you have that label on your mind do you believe?

A. Because the original Vasostrict of 12-month shelf life at room temperature, it was never marketed, and also the claims, pending claims on this declaration is related to refrigerated storage of vasopressin.

THE COURT: What did you say what? Related to what?

THE WITNESS: The pending claims, the declaration was related to refrigerated vasopressin.

THE COURT: Refrigerated.

BY MR. RHOAD:

Q. Now, did you subsequently learn that the label that the Examiner cited was not the label you had in your mind, but was the original label from April of 2014?

A. Yes. I learned while preparing for my deposition.

Q. Now, does knowing the fact that the Examiner had referred to a different label than the one you had in mind change your belief that you had, in fact, invented the subject matter of the label that is, in fact, recited in paragraph 7?

A. No, it does not change my belief because regardless of which label I'm referring to, I have contributed, so I believe it's correct and accurate.

Q. **The second-to-last sentence refers to refrigeration of the diluted vasopressin for up to 24 hours.**

Do you see that?

A. **I see that.**

Q. **Was that in the original label as well as the subsequent label?**

A. **Yes. Same information is there on the label.**

Q. **And that is information came out of the work you had done?**

A. **Yes.**

Q. **Okay. Now, switching gears to a different declaration, now, do you understand that Par also sought patent protection relating to the work you did on reformulated Vasostrict?**

A. **Yes.**

Q. **And did you submit declarations in connection with the prosecution of those patent applications as well?**

A. **Yes.**

Q. **Okay. If you could turn then, if you would, please, to DTX-1073.**

A. **Okay.**

Q. **Okay. This is a declaration that you signed in connection with one of those patent applications?**

A. **Yes.**

Q. **Okay. And when did you sign this declaration?**

A. **It was signed 22nd May 2017.**

Q. **Now, the defendants during the presentation, I believe it was Dr. Chyall, had raised some questions or concerns about some of the data that it was presented in a couple of paragraphs in his declaration, so I wanted to take you to those paragraphs. So if you would turn, if you would, please, to paragraph 29 of the declaration.**

A. **Yes.**

Q. **And what is described there?**

A. **It states Figure 5 to 6, provide direct comparison of the total impurities observed in pH 2.5 to 3.4 vasopressin formulations with those observed in the pH 3.5 to 4.5 vasopressin formulations.**

Q. **And were there, in fact, two different pH studies done at different times that this paragraph is referring to?**

A. **Yes. There are two separate experiments done at different times.**

Q. **And let's look at the next paragraph, paragraph 30. Can you tell us what that paragraph is describing?**

A. **Paragraph 30 is describing Figures 7 to 8 provide normalized plots comparing the assay observed in the pH 2.5 to 3.4 vasopressin formulations with those observed in the pH 3.5 to 4.5 vasopressin formulations.**

Q. **And it references that the normal -- that they are normalized plots. Can you -- does the paragraph also talk**

about that?
A. Yes. The reason why the data was normalized is discussed in the same paragraph. The document states that the data were normalized and presented as percent assay decrease of vasopressin over the four-week study period, rather than absolute assay, because the amount of starting vasopressin varied between the pH 2.5 to 3.4 vasopressin formulations and the pH 3.5 to 4.5 vasopressin formulations.
Q. And in general, when you're normalizing data, what does that mean to normalize data between two different studies?
A. Since the starting values were different between these two studies, it was not easy to make a direct comparison, so when we normalized the data, we are bringing all of the values to a common case, so the data becomes comparable across the two studies.
Q. Now, did you, in paragraph 29, does it say that the total impurity data is normalized?
A. No, it doesn't say that.
Q. Okay. And was the data and plot in Figures 5 and 6 normalized?
A. No, they were not.
Q. Okay. And why did you present non-normalized data for total impurities but normalized data for the assay

value?

A. As I specified earlier for the assay, the starting values were different between the two studies. Normalization was preferred to bring all of the data into a common scale. However, that is not necessary for percent impurity because percent impurity is also represented percent of amount of vasopressin in the, in the formulation. So there's no need to actually convert that into another normalized value.

Q. Now, did the Patent Office have all of the raw data that was underlying the graphs that were presented in Figures 5 and 6 of your declaration?

A. Yes. Patent Office had all, all of the raw data submitted in earlier declarations.

Q. Okay. Now, with that data in hand and looking at Figures 5 and 6, would one be able to tell whether or not the figures in 5 and 6 presented normalized data?

A. Yes. One would be able to easily say because they have raw data in table and the scale and the figure clearly label that percent impurity.

If they are looking for comparison of raw data for each formulation, the numbers in the data table would match the data in the graph because they are not converted into other forms.

Q. Okay. So let's take a look then, if we could, at

Figures 5 and 6. I think they're on pages 11 and 12.

A. **Yes.**

Q. **And so I think what you are telling me is, each of these dots that you see on 5 and 6 come directly from the raw data that was provided?**

A. **That is correct.**

Q. **And is that true for Figure 7 and 8?**

A. **Figure 7 and 8 are normalized data. I don't recall if the normalized values were present in one declaration in the granular form. If not, then it -- we may not find the same values in the figures, but looking at the scale, the Y axis scale, it clearly says that a percent assay decrease. Figure seven.**

Q. **Okay. All right. Let's turn then, if you would, please, to paragraph 32 back on page 18.**

A. **Yes.**

Q. **And I'd just like to read into the record the first sentence. It says, as described above, because the procedures for each of the experiments were the same, and because pH was the only variable that was not normalized, I conclude that the differences in the assay, in parentheses, percent label claim, vasopressin remaining, and percent total impurities results for each formulation were attributable to changes in pH.**

Do you see that?

A. **Yes, I see that.**

Q. **And, first of all, did you believe that that conclusion and sentence were true at the time you signed the declaration?**

A. **Yes, I believed.**

Q. **Now, when you are referring to as described above, what were you referring to?**

A. **So this refers to earlier paragraphs in the declaration where -- where I was trying to address a question from the Examiner, asking if the observed differences between different pH values, whether it was true, or is it due to the fact that the data came from two different experiments.**

So I have presented all of the analysis and earlier paragraphs where I looked at how the study was conducted between the two studies, what variables are kept constant and which part is different between the formulations and how the stability study was done, how the samples were -- I'm sorry, how the samples were tested.

So based on that, what I'm saying here is that all the variables have input into the experiments, were kept constant and was the only difference between formulation.

So the effort we observed between formulation is true on the output, that is the data that you are seeing, total impurities and assay are thoroughly due to the fact

that the pH is the only difference between the formulations.

Q. Now, you say pH was the variable that was not normalized. Is that consistent with what you said above in 29 and 30, where the data for assay value was normalized but the data for total impurities was not?

A. So when I'm referring to data in paragraph 30, normalization reference refers to three things of data to convert into a common scale whereas in this paragraph, 32, when I said it was not normalized, that means the pH was not the constant between formulations. All other input data was very common.

Q. And in paragraph 32, you are talking about the variable not being normalized as opposed to a plot being normalized or data.

Is there a difference between normalizing data between normalizing a variable, an input variable?

A. Yes. So as I just mentioned, when we talk about normalizing data, we are treating the output data into, into some kind of mathematical equation to bring them to a common scale whereas when I'm talking about input variables, normalized or not, I'm talking about whether that variable was kept constant or not.

Q. All right. Now, very quickly, if you could turn to PTX-330.

A. Yes.

Q. **Okay. Is this another declaration that you signed?**

A. **Yes.**

Q. **And when did you sign that one?**

A. **I signed it March 31st, 2016.**

Q. **And if you could take a look at paragraphs 13, 14 and 16 and just confirm that you are presenting there the same or at least similar information relating to the paragraph we just looked at in your other declaration.**

A. **Yes. This is similar information. It was earlier than the declaration.**

Q. **Okay. And I understand that that's another declaration that the defendants are challenging in this case and all of your testimony that you just gave about DTX-1073 would apply as well to the statements that you made in this declaration; is that right?**

A. **That's right.**

Q. **Relating to those paragraphs?**

Now, do you know whether you ever prepared a normalized plot of the data for total impurity.

A. **I had forgotten about it. Then it was -- an e-mail was shown to me at the time of deposition. Then I realized that I had, in fact, calculated normalized value for total impurity.**

Q. **And do the conclusions that you expressed in your declarations about the optimal pH and impact of pH change if**

the total impurity data is normalized versus not normalized in your view?

A. **No. My conclusion is still the same, whether the percent impurity data is normalized or not.**

Q. **Let me just conclude by asking you, you know, there are three declarations that have been -- of yours that have been challenged in this case and did you believe at the time you signed those declarations that they were truthful and accurate?**

A. **Yes, I believed they were truthful and accurate at the time of signing.**

Q. **All right.**

MR. RHOAD: No further questions. I think most or all of these are already in evidence, but just for the record, if they're not in evidence, we move PTX-329, PTX-372, DTX-1073 and PTX-330?

MR. HALES: No objection.

THE COURT: All right. They are admitted.

(PTX-329, PTX-372, DTX-1073, and PTX-330 were admitted into evidence.)

MR. RHOAD: May I approach, Your Honor?

THE COURT: Yes.

CROSS-EXAMINATION

BY MR. HALES:

Q. **Good morning, Dr. Kannan.**

A. **Good morning.**

Q. **My name is Bryan Hales. I've got a few questions to follow up on Mr. Rhoad.**

One of the documents that Mr. Rhoad asked you about was the declaration regarding the 2014 Vasostrict label.

Do you remember that?

A. **Yes.**

Q. **Now, at your deposition when you were being questioned about your declaration that related to that label, you had the exhibit in front of you, which was the 2014 Vasostrict label; is that right?**

A. **That is correct.**

Q. **If we could pull up DTX -- well, let me back up. Do you agree that you and Mr. Kenney did not invent all of the information in the 2014 Vasostrict label?**

A. **I don't have a recollection of Matt Kenney's contribution, but I agree that I have contributed to all of that information.**

Q. **There's multiple things that are listed in the labels. Can we agree that you did not contribute to all of the information provided in the label?**

A. **So I would like to clarify. My contribution was related to the value of vasopressin, and if we look at it as a subject matter, it conveys that as a combination of all of**

the information along with diluted vasopressin.

Q. And the elements other than the one that you identified with respect to diluted vasopressin, those other elements you did not contribute to; is that right?

A. That is right.

MR. HALES: Could we have PTX-329 up and go to page 2, paragraph 7.

BY MR. HALES:

Q. Now, Mr. Rhoad asked you some questions about the first sentence of paragraph 6. Do you remember that? The second sentence he didn't ask you about.

Let's take a look at that one. The second sentence, I take it, you would agree is, as you now -- as you understand not correct with respect to all of the information in the 2014 label; right?

A. Could you please repeat your question, counsel?

Q. Well, the sentence says, Matthew Kenney and I invented the subject matter of the label that is cited in the office action.

Do you see that?

A. I see that.

Q. And the label cited in the office action is the April 2014 Vasostrict label; is that correct?

A. Correct.

Q. Okay. You and Mr. Kenney did not invent the subject

matter in that label; is that correct?

A. I do not know Matt Kenney's contribution to the subject matter on that label.

Q. But you didn't invent the subject matter in that label; is that correct?

A. I invented the subject matter in the label because I have contributed to that label.

Q. Just the refrigeration part?

A. I have contributed to the refrigeration part and the subject matter in my opinion includes refrigeration of diluted vasopressin and other information cited on the next paragraph.

Q. And to be clear, the sentence Mr. Rhoad asked you about was about the currently pending claims; right?

A. Yes.

Q. The sentence I'm asking you about is the content of the 2014 Vasostrict label.

Do you understand that?

A. Yes, I understand that.

Q. Now, you were also asked a question about the normalization declaration on direct; right?

A. Yes.

Q. So let me just ask you a couple questions.

So in your declaration you talked about the assay and today you talked about assay experiments and

impurity experiments; right?

A. They are two separate experiments, but both assay and impurities were calculated on the -- on the formulations.

Q. When you talk a measurement of the total assay at the end of an experiment, you're measuring whatever the assay amount is at that moment; right?

A. That's right.

Q. Okay. And in an impurities experiment, total impurities experiment, when you measure impurity at the end of the experiment, the value you get back is the total number of impurities in the material at the end of the experiment; is that correct?

A. And expressed that, the amount of active in that formulation.

Q. But you're measuring -- whatever the impurities are that are there at the end of the experiment; correct?

A. Measuring all of the impurities as a percent.

Q. Okay. Sometimes at the beginning of an experiment when you are talking about assay, there's a certain amount of material in the, in your sample; is that correct?

A. Correct.

Q. All right. And so if you want to know what happened to the assay during the time of the experiment, you would subtract the assay value at the end from the assay value at the beginning; is that correct?

A. **If I want to see the difference.**

Q. **The difference that occurred over the time; right?**

A. **Right.**

Q. **All right. For percent total impurities, if you want, you also at the start of the experiment have some total impurities in the sample; correct?**

A. **Correct.**

Q. **All right. And so if you want to understand the number, the amount of impurities that occurred during the experiment, during the time of the experiment, you subtract the total impurities measured at the end -- sorry. You subtract the impurities that were there at the beginning from the ones that were there at the end; is that correct?**

A. **Yes, we can do that.**

Q. **That is the way to understand the amount of impurity that came into being during the experiment; is that correct, sir?**

A. **But in the context of the declaration provided for the data submitted in --**

Q. **Dr. Kannan, in the interests of time, my question was a scientific one?**

A. **Yes.**

Q. **In order to understand the amount of total impurities that came into being during the experiment, you need to subtract the ones that already existed at the beginning of**

the experiment from the total amount that existed at the end of the experiment; correct?

A. **Yes, that's one of the ways to do it.**

Q. **Well, the impurities that were there at the beginning of the experiment don't disappear during the experiment; correct?**

A. **Correct.**

Q. **And so if you had more impurities at the beginning of experiment A than you did at the beginning of Experiment B, and all you looked at was the total amount of experiments -- impurities that were at the end of each experiment and compare them, that wouldn't necessarily tell you -- it wouldn't tell you how many actually arose during the experiment; right?**

A. **Could you please repeat your question, counsel?**

THE COURT: Do you want it read back?

MR. HALES: No.

THE COURT: You're not going to repeat it?

MR. HALES: No. In the interests of time --

THE COURT: Look, I took some time. Don't worry about losing five minutes. If you want to ask the question, ask the question.

MR. HALES: Okay. Understood. I appreciate that.

BY MR. HALES:

Q. **So if you have, you have two different conditions that you're testing and you want to understand which one produced more impurities over the course of the experiment than the other, are you with me so far?**

A. **Yes.**

Q. **Okay. And one of them starts -- one sample starts with more impurities than the other sample does. Okay? And all you look at to compare the two is the total amount of impurities that were present at the end of the experiment for each of them. You're not going to get an accurate understanding of what happens during the course of the experiment; right?**

A. **It depends on what the difference is.**

Q. **Dr. Kannan, you recall being deposed in the case Par versus Eagle, right?**

A. **Yes.**

Q. **Okay. At that time of that deposition, you understood that you were under oath; right?**

A. **Yes.**

Q. **And you -- is it correct that at that deposition, you testified truthfully?**

A. **Yes.**

MR. HALES: No further questions, Your Honor.

MR. RHOAD: No questions, Your Honor.

THE COURT: All right. I've got a couple of

questions.

THE WITNESS: There were, what, three affidavits, three declarations, I think, that you signed. Is that right?

THE WITNESS: Yes. There were more, but three, yes.

THE COURT: Did you write the declarations?

THE WITNESS: I did not write directly. Drafted by legal department, Your Honor.

THE COURT: Did you read the declarations before you signed them?

THE WITNESS: Yes, Your Honor, before I signed them.

THE COURT: Take the first declaration. How long did you spend reading it before you signed it?

THE WITNESS: I don't have a recollection, Your Honor, but I read it before signing it.

THE COURT: Was it more than an hour?

THE WITNESS: I don't have a recollection, Your Honor.

THE COURT: Was it your idea to discuss normalization in paragraph 7?

THE WITNESS: It was a team idea and the fact that data was already presented in advance of the declaration and I was providing response to Examiner's question asking whether the difference observed in the curve

is due to the fact that it's the effect appears or is it the fact there were two separate experiments.

So to explain that, once we had already provided normalized data and I was providing additional explanation on what is is then and what does it mean.

THE COURT: Did you understand that the Patent Examiner had questions about the limitations?

THE WITNESS: Yes, Your Honor.

THE COURT: Did you understand -- did you think the Patent Examiner had concerns about the pH limitations?

THE WITNESS: Yes, Your Honor.

THE COURT: What was your understanding of why paragraph 7 was submitted to the Patent Examiner? I want to make sure --

MR. RHOAD: Your Honor, I think you might be confused between the two.

THE COURT: Yes. I've got to make sure. So I want to look at PTX-0329.

MR. RHOAD: And that doesn't have anything to do with normalization.

THE COURT: Sorry. I got the wrong one. And I got the wrong paragraph, so that's right. Thank you very much, Mr. Rhoad.

So why don't you look at DTX-1073. Actually, hold up. I apologize.

I want to go back to paragraph 7 of PTX-0329. Can you look at that first?

THE WITNESS: Yes.

THE COURT: Why did you think that this paragraph had to be presented to the Patent Examiner?

THE WITNESS: Because the paragraph was cited by the Patent Examiner as prior art in the office action later.

THE COURT: Because of the paragraph?

THE WITNESS: No. The label. The Examiner stated that the label that is on FDA's website is the prior art and the Examiner goes on and explains that the label.

THE COURT: So you knew -- was paragraph 7 submitted, as far as you understand, to overcome the Patent Examiner's concern about the label being prior art that would invalidate the patent?

THE WITNESS: Yes, Your Honor.

THE COURT: All right. Then look at paragraph 32 of DTX-1073. And what was your understanding of why paragraph 32 had to be presented to the Patent Examiner?

THE WITNESS: The Patent Examiner had concern that the data came from two different experiments. Wanted to know the effect that we see on that impurity. Was it truly significant or whether it is due to the fact that the experiments, these were two separate experiments. That was the purpose of the paragraph to explain to the Examiner.

THE COURT: All right. Thank you. Anything else?

MR. RHOAD: No, Your Honor.

THE COURT: Thank you.

THE WITNESS: Thank you, Your Honor.

(Witness excused.)

MR. LOEB: Your Honor, Par calls Dr. Lee Kirsch, who you heard from earlier. He's going to present Par's responses to the defenses of invalidity and inequitable conduct defenses.

MS. WU: Your Honor, I think there were -- there was an objection that we had flagged earlier. I'm wondering if we should discuss that with the witness?

THE COURT: Well, now we'll have sidebar.

MS. WU: Oh, okay.

... LEE KIRSCH, having been previously duly sworn as a witness, was examined and testified further as follows ...

THE COURT: And, Dr. Kirsch, I will remind you, you remain under oath. You can have a seat up there. All right.

(Sidebar conference held as follows.)

MS. WU: The issue is that we decided not to call Dr. Marais to streamline the case. As you know, he would have been presented on one issue regarding invalidity.

THE COURT: Okay.

MS. WU: Dr. Kirsch has some rebuttal opinion to Dr. Marais, which of course involves talking about Dr. Marais' opinion.

Now, we're not calling Dr. Marais, so we don't think it's appropriate for them to put in Dr. Marais' opinions because they're rebuttal opinions. There's nothing to rebut here because Dr. Marais is not here. Dr. Kirsch provides other statistical analyses. That's kind of, here's my statistical analysis. We don't have a problem with that.

THE COURT: You don't have a problem with presenting it?

MS. WU: With them presenting the statistical analysis that Dr. Kirsch came up with. We would have an issue with is him talking about, rebutting an opinion that was never presented.

THE COURT: All right.

MR. LOEB: So just for context, Dr. Marais was a defendants' expert who was disclosed in the normal course, and he had been identified as a witness to testify in this case as recently as last Tuesday, and it was last night, about 11:00 p.m., where they decided to withdraw him as a witness.

THE COURT: Can I ask you, why is that relevant?

MR. LOEB: I will get to the most relevant part.

THE COURT: Well, wait. Get to the other, because why is it relevant when they withdrew it? I just want to figure it out.

MR. LOEB: So my point is I'm not going to try to introduce any evidence, admit any evidence from Dr. Marais and under Rule 703, going to have Dr. Kirsch rely on the calculations that Dr. Marais did, which are the types of hearsay which are considered appropriate for an expert to rely on. In other words, they are reliable types of information which he, Dr. Kirsch, would rely on.

THE COURT: That doesn't answer the question of time. I want to understand the timing.

Suppose they withdrew him before trial. You led off with timing. That suggests to me that it's important.

MR. LOEB: Simply to give you context of what has happened here, because obviously, Dr. Kirsch --

THE COURT: I thought you might say, for instance, you prepped the witness yesterday at 5:00 o'clock and at 11:00 o'clock at night they withdrew, so this is a presentation. But that's not it. And it seems to me that this issue probably has arisen before.

Do either of you have case law?

MR. BLACK: Your Honor, there's a different issue. It's much simpler actually in a way. Dr. Kirsch -- Dr. Marais is a statistician.

THE COURT: Yes.

MR. BLACK: He testifies a lot. He did a statistical analysis. There's one data point in his report which he calculated that we like.

Dr. Kirsch gave a report in a case where in his paragraph he described a statistic calculated by Marais, said it was valid, and said this is the significance.

So there's an expert who is going to rely on material that was developed during the course of the case. It's the type of information that experts normally rely on under 703 and therefore he can testify to it.

We don't need to admit Dr. Marais' evidence because it's the type of information that experts rely on and it was developed during the course of the case.

THE COURT: So when you say it's the type, and this is why I said I will bet you there's case law on this.

MR. BLACK: This is very clear on this one. People like Dr. Kirsch and Dr. Park, when they do their work, sometimes they farm out certain statistical analysis that are particularly complicated to statisticians who do that work and then they rely on the numbers that are computed by statisticians. Ms. Wu is shaking her head yes.

THE COURT: Hold on.

MS. WU: Sorry.

MR. BLACK: So the statisticians will do an analysis. They come up with a number, and then the experts, the POSAs look at that number along with all the other information and make an evaluation.

Dr. Kirsch noticed it when Dr. Marais did his analysis. He came up with one data point which is very helpful for us and he put it in his report, so he's testifying within his report about a data point that was created during the course of the case that falls squarely within, you know, 703, and he should be allowed to testify to the extent only of his report.

THE COURT: Yes?

MS. WU: So with regard to experts who are relying on testimony and that being an exception, fine, but that's not the case here. This is exactly, we can go through it.

I think Dr. Kirsch is wrong, but he criticized Marais, "it's wrong, it's flawed, it's everything bad." So how can you say this is the stuff he's relying on when I can show you page after page, it feels like of "flawed, bad, bad methodology."

THE COURT: Right.

MS. WU: Again, I disagree with that in substance. But you can't have it both ways, that you criticize him in your report and now you say, "oh, it's

reliable and it's the type of stuff I am supposed to rely on."

MR. BLACK: There's nothing --

THE COURT: Actually, can I ask, everybody direct your comments to me as opposed to each other and that's how we do things here. It makes it a lot easier for the court reporter. Go ahead.

MS. WU: And the last point, of course, is whatever they want to put in regarding Dr. Marais' opinions is hearsay. They're offering it for the truth of the matter asserted. It's an out-of-court statement offered for the truth of the matter asserted, so they can't get around that, and they can't get around this exception that Mr. Black is talking about because that is not the reliable sort of work based on Dr. Kirsch's own words in his expert report.

THE COURT: So I'm pretty confident there's case law out there that deals with what happens when you have a testifying expert who is withdrawn and the extent to which it can be used, the prior statements by the expert in court.

Is anybody familiar with those cases?

MR. LOEB: Yes.

THE COURT: Maybe give me one so I can look at it.

MR. LOEB: Sure. I think the case you're

thinking of--

THE COURT: I wasn't thinking of one case.

MR. LOEB: Oh.

THE COURT: I'm thinking of just a body of case law.

MR. LOEB: Right. I believe that body of case law that you are thinking about has to do with admitting testimony of an expert who is withdrawn.

So there's case law particularly where an expert was withdrawn on the eve of trial and the other side wanted to play some portion of the deposition.

THE COURT: Right. Actually, it's funny, because my recollection is a lot of this case law deals with whether it's an authorized statement.

MR. LOEB: Right.

THE COURT: Whether it's admission by a party opponent.

MR. LOEB: Exactly.

THE COURT: I think there's some variation. Kind of my own personal inclination would be to say it's an admission by a party opponent, but I think the majority of the case law is against that position.

MR. LOEB: I think -- I think the case law is admitted, but the reason why I didn't bring it up initially is --

THE COURT: You're not going to admit the testimony itself. I get that, but I just want to at least stress that issue first.

MR. LOEB: Yes.

MS. GAZA: Your Honor, we have Third Circuit authority and District of Delaware authority, Your Honor. We have copies for counsel as well.

THE COURT: Right. Just tell me the cite to look at in the Third Circuit law. I don't really care about the district case.

MS. GAZA: Third Circuit, Your Honor, is the Kirk versus Raymark Industries. You can look at it. I believe it's 164. Is that correct?

MS. WU: Yes.

MS. GAZA: Yes. 164, the top right column and bottom left column on 164.

THE COURT: I'm going to put everybody on hold. Let's go do this. We've got too many people and you're all uncomfortable.

MR. BLACK: It's ten of, Your Honor. This will probably take more than ten minutes.

THE COURT: I think that's smart. We'll pick up with 164.

(End of sidebar conference.)

THE COURT: Doctor, you may be excused.

(Witness excused.)

THE COURT: Okay. And thank you, Ms. Gaza, for refreshing my recollection, and sure enough, the Kirk opinion holds exactly what you said it does and is actually consistent with my recollection that I can't probably do what I normally would do.

The idea that an expert's testimony in the case constitutes an admission by a party opponent is not the law of the Third Circuit. And Mr. Loeb acknowledges, it seems to me, that, in any event.

And your argument is, as I understand it, that you're not seeking the admission of testimony. This is a hearsay statement, but it's appropriate for an expert to rely on hearsay, at least in certain circumstances, and that is pretty much what is going on here.

And Mr. Black argued that essentially, the analysis that was performed by Amneal's expert, the statistical analysis, is the same type of analysis that Dr. Kirsch could have had his associates perform and therefore it's the type of information upon which an expert issue would normally and I think routinely rely. Therefore, it should be admissible under 703.

I want to hear from the parties. I think the dispositive kind of question is would you, in fact, normally rely on this type of information when, and --

MR. BLACK: He'll lay that foundation.

THE COURT: Okay. But let me ask you this: Did Dr. Kirsch have his associates perform the same type of analysis that -- what's your expert's name?

MS. WU: Dr. Marais.

THE COURT: That Dr. Marais performed and on which you now wish to rely?

MR. LOEB: So, Your Honor, first of all, Dr. Kirsch is actually quite knowledgeable in statistical analysis, so when Mr. Black said that Dr. Kirsch would have to rely on somebody else to perform this kind of analysis, that wasn't exactly correct.

THE COURT: I didn't mean he would have to rely. I'm saying I think the argument -- it was good argument to make, which is that experts routinely employ associates and go out and do the mathematical calculations.

MR. LOEB: Right.

THE COURT: That's what I took that argument to be.

MR. LOEB: Right.

THE COURT: That argument led.

MR. LOEB: So Dr. Kirsch evaluated, is capable of, he did evaluated Dr. Marais' calculations and certainly has some criticisms of his reported methodology, but not the calculation.

So it's Par's position this would be no different than an expert reading in a scientific article about some result by some colleague in the field and being able to generate an opinion.

THE COURT: Right. So let's say, let's just posit that I agree with you. In other words, the types of calculations performed by Marais are the type of calculations that experts routinely rely on and therefore could rely on here. And I think you would agree that Dr. Kirsch could not go out and have discovered three days ago that some other expert in an article performed the types of calculations, and you couldn't bring that in here, right, because it wasn't mentioned in his report. You agree with that?

MR. LOEB: Yes, I do.

THE COURT: So what I'm trying to figure out, I have to believe there's case law. Does it make a difference that Dr. Kirsch didn't rely on it until it was a rebuttal report as opposed to his opening report? In other words, I've got to believe there's case law that talks about whether something that is solely in a reply expert report is admissible when the other side's expert to whom the reply was made is no longer part of the case? Does anybody have case law on that?

MR. LOEB: Your Honor, that's not the situation

here.

THE COURT: Well, Marais is not testifying.

MR. LOEB: That part is the situation. The way that you have characterized which report is not correct.

THE COURT: Okay.

MR. LOEB: There was an opening report in the Amneal case by Dr. Kirsch. That related to infringement and this particular issue that we're talking about now, Dr. Kirsch can testify about, has to do with invalidity.

THE COURT: Okay.

MR. LOEB: So Dr. Maris presented an opening report.

THE COURT: Right.

MR. LOEB: In Dr. Kirsch's rebuttal report --

THE COURT: I'm sorry. I was using this synonymously. In other words, he has only proffered the opinion in response to Marais' opinion. I don't care whether it's a rebuttal reply.

The point is, it was a response as opposed to an opening opinion, and I've got to believe there's case law where the Court has had to address what to do when the response opinion is proffered, but the expert report to which the response is made is no longer part of the case. And do you have any cases that say that?

MR. LOEB: I do not have any cases.

THE COURT: Does anybody have any cases that address that situation?

MR. LOEB: One more point about the situation is of course, Dr. Marais did not disclose his opinion to us until his opening report, and so how could Dr. Kirsch have had a reaction to them until we saw them?

MR. BLACK: And the issue arises because of the combination of the cases, Your Honor. If Amneal did what they have just done, withdraw their invalidity expert in a case where we were in the courtroom together and those were the only two parties, their validity case would fall and we'd be entitled to JMOL, but because the defendants have submitted a combined case selecting what they wanted, we're now -- we would be deprived of a piece of evidence that's in a case and the pretrial order says experts are entitled to testify what's in their report.

If he is still in the room, I am willing to put Dr. Marais on the stand and elicit a statement, but I don't think that should be necessary.

THE COURT: All right. Anything else, Ms. Wu?

MS. WU: A couple more points. What they are putting here is beyond the scope of what we put in in our validity case, again, by streamlining it. And, second, one big issue here is fairness.

Par wants to talk about one, they've

cherry-picked one data point.

THE COURT: How about this. I will let you call Marais in rebuttal. I will give you the extra time.

MS. WU: So here's one more complication, Your Honor. Dr. Marais, and prior, you know, to coming here, made a return flight for later this afternoon. He is -- has to leave.

He was supposed to testify this morning, so we thought the timing would work out. This is a complication we did not foresee. I think if it's an issue of calling him, I think for his travel convenience, you know, he is here for him to come in. We don't think it's appropriate because, you know, we didn't put him on, it's rebuttal testimony. It doesn't fit in the hearsay objections.

They are cherry-picking here one data point. You know, he had to come in and put in his methodology, explain everything, explain all the data points. They just want to have him talk about one, so I think there's also a fairness issue.

MR. BLACK: I have a solution, Your Honor. There's one data point. It's just a linear regression analysis, basic statistical stuff. There's one data point that was statistically significant. That's what we want to put in.

He's here. Go for lunch, come back at 12:30. I

will call him in our rebuttal case. Our pretrial order permits us to call witnesses, any party that's listed. I will put him up. I will ask him a question, I will put it in.

THE COURT: Well, I will say this. So one reaction I have is unless anybody is going to challenge Mr. Black's reading of the pretrial order, I think that may -- his reading of the pretrial order, if it's accurate, I have every reason to believe it is -- if he answers the question, and I think that, again, and people need to quickly look. If the pretrial order says any expert can rely on anything in anybody's report, that answers the question.

MR. BLACK: Yes, it does.

THE COURT: As far as I'm concerned. And if the pretrial order says either side can call anybody's witnesses who is here.

MR. BLACK: I think that will take care of it.

THE COURT: Do you all want to look at that?

While they're looking, Mr. Loeb, can I ask you this? Is this part of Kirsch's testimony? You know, maybe could you present it up front and then if Amneal wants to call their expert quickly in response on that aspect of it, we could go that way? I mean, how are you structuring your direct?

MR. LOEB: I certainly did not intend to do that.

THE COURT: Really?

MR. LOEB: Of course, it won't make a lot of sense without the context of --

THE COURT: No, I'm not talking -- you have to give it context. I just meant was it coming up at the end of the testimony?

MR. BLACK: It's an invalidity point.

MR. LOEB: It's kind of in the first third, perhaps. It's definitely not at the beginning.

THE COURT: So maybe, like, if you had to ballpark it, how long do you get to that third?

MR. LOEB: 45 minutes.

THE COURT: Okay.

MR. BLACK: Here's what it says.

THE COURT: Hold up, Mr. Black. I have a conversation going with your colleague.

MR. BLACK: I know. I can't help myself. I will go stand over here again.

MR. LOEB: After 10 or 12 years now, I can attest to that, Your Honor?

THE COURT: So I'm just wondering, I want to hear from Ms. Wu, but I mean maybe you do the 45 minutes of testimony with him, then you break, and Amneal gets to

present him, you know, to go after that part and then they finish and then their expert leaves and then you continue with him. That would be one thing.

I don't know what you think. You wouldn't have to call him. It depends on how the testimony comes in.

MS. WU: All right. I'm sorry, Your Honor. You're suggesting that -- I was trying to look up --

THE COURT: That's fair. I saw you over there.

Just so people know what we're talking about in the transcript, you were busy working on some --

MS. WU: Locating the relevant portion of the pretrial order.

THE COURT: Right.

MS. WU: But I think I overheard some of the discussion.

THE COURT: So while you did that, what I was wondering is, maybe what we should do is have Dr. Kirsch testify, and when he gets to the part about where he references Dr. Marais?

MS. WU: Marais. He'll tell us how to pronounce it.

THE COURT: Marais. When he gets there and kind of finishes up that section, then at that point you get to cross him and call, you know, Dr. Marais just to address that issue.

Is that acceptable? Frankly, you may not want to call him, but you could at least decide.

MS. WU: Exactly.

THE COURT: I'm not sure how much this is going to matter. I think this would be very interesting to see.

MR. LOEB: We are talking about two to three minutes of testimony here, Your Honor.

MS. WU: Well, this is I think the issue. It's very limited, but for Dr. Marais to have to explain what they're cherry-picking is not going to be short. His presentation was going to be longer than a few minutes.

So this is the problem where they've cherry-picked one data point. He has simply -- you know, to talk about one thing out of context. To me, it's quite complicated. I think that's why in terms of presenting his methodology, it was not a short few minute presentation, and so, you know, just to have this kind of ask one question is simply not fair. You have to step through the --

THE COURT: This goes to invalidity? This goes to what?

MR. LOEB: To criticality.

THE COURT: To criticality?

MR. LOEB: Yes.

THE COURT: All right.

MR. LOEB: So Dr. Kirsch is going to be able to

establish that the information we've been looking at in the declaration establishes criticality.

Dr. Marais did an independent statistical analysis of those data plus some additional internal data at Par, and in his statistical analysis he is concerned that there's a statistical difference between pH 3.6 on the one hand and the range of 3.7 to 3.9 on the other, and that's confirmatory of both what the declarations say and what Dr. Kirsch's independent statistical analysis done a different way also finds.

THE COURT: All right. Hold on.

MS. WU: And --

THE COURT: Just give me a second. I hate to do this to you, but since I don't have realtime, could you just repeat that?

MR. LOEB: I'm not exactly sure what I said, but I will do my best.

So Dr. Marais performed a statistical analysis and data that he found in Par's declaration, some of which you've seen.

THE COURT: This is the November and the March study?

MR. LOEB: That's correct.

THE COURT: Yes.

MR. LOEB: He also found another internal

laboratory notebook record of an additional study.

THE COURT: Okay.

MR. LOEB: He combined the information from those places and he conducted what he felt was the appropriate statistical test to ask whether there was a difference between the rate of impurity formation at pH of 3.6 on the one hand versus the rate of impurity formation over the range of 3.7 to 3.9.

THE COURT: Right. Can I just ask: You know, Mr. Black asked a question yesterday to Dr. Chyall, and my recollection is, and the transcript will be what it is, but he said basically, it's the data -- maybe I'm conflating things here, but essentially, I thought he basically acknowledged that whether you looked at the 3.4, the 3.6, 3.7, the result would have been the same from the Patent Examiner. Hold on.

MR. BLACK: That's on materiality. This is on obviousness, criticality is the range, and is the range critical over other prior art like a 3.6 product.

What he -- what Dr. Chyall testified to was even if the normalization data had been provided to the Examiner, if a normalized plot had been provided, it wouldn't have mattered.

THE COURT: I'm conflating. That's not a criticality issue.

MR. BLACK: Right. The issue here is where we've got things in Dr. --

THE COURT: All right. You know what, if you are telling me that's not criticality, fine. I thought it would be, but all right.

MS. WU: Your Honor, I just need to respond to a couple things Mr. Loeb said.

THE COURT: Please.

MS. WU: First, he identified one additional problem. He talked about how Dr. Marais pooled two sets of data. One is the set you're familiar with from the prosecution history. The second is from Par's lab notebook.

This was that supporting testimony I had referenced that Dr. Winter was going to give to explain how these two are very similar and therefore it's appropriate then for Dr. Marais to pool it. So kind of as a foundation matter, they kind of go hand in hand.

We didn't put Dr. Winter to talk about why it's appropriate for Dr. Marais to pool. Dr. Marais did pool the data, he came up with an analysis. They keep talking about this one data point. But to be clear, the slide that they point out showed there were three conditions under which Dr. Marais analyzed this situation, and under two of the three, it was not statistically significant. Of course, he can come in and explain the one they're looking at is the wrong

one to look at, but this is kind of the fairness issue I was trying to identify.

THE COURT: I'm trying to address the fairness. He's here. You know, it's their case, so they could call him or we can -- you can have him wait, and if you want after we have 45 minutes or so of the testimony and the disputed issue has ended, we can take a break. You can decide whether you want to call him.

What would you prefer?

MS. WU: I think if you are inclined --

THE COURT: I'm inclined to let it in because I've got the funny feeling it's all not going to matter anyway is my guess. There's a lot of other things I think --

MR. BLACK: It's also resolved by the pretrial order, Your Honor.

THE COURT: That's what I'm saying. It's resolved by the pretrial order. Sorry. I didn't hear the final confirmation.

MR. BLACK: What happened to that page?

MS. WU: So, Your Honor, about that one kind of foundational issue, I hope it's not being used against me that I didn't put Dr. Winter up to lay the foundation that these two formulations Dr. Marais looked at are essentially the same.

THE COURT: Well, Dr. Marais can rely on what Dr. Winter said, can't he? He's an expert.

MS. WU: Yes, but Dr. Winter didn't testify. But, yes, there was an expert report.

THE COURT: I assume Dr. Winter isn't going to testify to anything he didn't put in the report before. Dr. Marais can testify what Dr. Winter did and go from there. You won't be prejudiced by that.

MS. WU: All right.

THE COURT: So confirmation of the pretrial order says what? What was represented?

MR. BLACK: That's the page about expert reliance on expert testimony.

MR. HALES: What paragraph and page?

THE COURT: I've got competing proposals here.

MR. BLACK: There's no difference on this point.

THE COURT: Oh, okay.

MR. BLACK: We'll have to rely on it.

THE COURT: What are you reading from?

MR. BLACK: Maybe I gave you the wrong page. I need to go look at the transcript or the pretrial order.

THE COURT: That's okay.

MR. BLACK: I think their proposal would allow us to do it as well.

THE COURT: What are you referring to?

MR. BLACK: This is about --

THE COURT: This is the Eagle, Par? Which one?

MR. BLACK: Amneal.

THE COURT: It has to do with Amneal. Sorry. And then what paragraph?

MR. BLACK: It's 56.

THE COURT: Okay. I don't think 56 says it. Do you want to point me to the language?

MR. BLACK: Well, 56 says we're allowed to rely on the reports.

THE COURT: Okay.

MR. BLACK: They had a counter-proposal which doesn't explicitly say that, but it says we can present a consolidated case, and I don't know if this -- I don't remember whether this was an issue at the pretrial conference or not. All right.

MS. WU: I don't see it.

MR. BLACK: I believe I have to look at the Eagle and I don't know what the answer is.

THE COURT: Normally, I think, I could be wrong, but you often do see a provision in the pretrial order that says either side can call the other witnesses.

MR. BLACK: Oh, yes, we have that. That we have. I was referring to the, we can rely on anything in the expert report.

THE COURT: Okay. So here is the thing. They can call your expert or you can call him, because the pretrial order -- wait. Yes. The Exhibit 9 of the pretrial order permits that.

MS. WU: Your Honor, in that case I can go with the suggestion because of the travel constraints to do it in the segment fashion you described.

THE COURT: We'll do that. Thank you very much. Try to condense as much as you can the beginning of the testimony to get to the point where you elicit or reduce the challenged testimony and get your opinions related to it.

You know, you get to do it with context and whatnot, but I'm sure you're about to get to it fast. Amneal will get to decide whether they want to cross the witness right away on that material or whether they want to call their expert to rebut it or whether they're going to make the conclusion that it wasn't really that damaging to the case and then let's go forward.

All right? Let's go. Let's bring Dr. Kirsch in.

MS. GAZA: Your Honor, could we -- you know, I think it may make sense for Dr. Marais to hear what Dr. Kirsch has to say about it. If we could have a few minutes to get him over here.

THE COURT: He's not in the building?

MS. GAZA: He's not in the building.

THE COURT: Let's keep it on the record. Where is he going? California?

MS. GAZA: He has to be at the airport at 2:30.

THE COURT: Okay. Do you think he's going to be able to get here very quick?

MS. GAZA: I think so. Just a few minutes.

THE COURT: Oh, okay. All right. Let's get him here. Let's do it real fast so he can be here.

Anything else we can talk about while we're waiting?

MR. BLACK: Yes. Just -- they should make the call.

THE COURT: Go ahead and make the call.

MS. GAZA: We are, Your Honor.

THE COURT: All right.

MR. BLACK: So we could start with Dr. Kirsch now and go --

THE COURT: Well, as soon as Dr. Marais gets here, you can start with Dr. Kirsch. If you want to do any background that doesn't relate?

MR. LOEB: Yes, that would be helpful.

THE COURT: Do you want to do that? You're going to have to switch gears though as soon as he gets here.

MR. LOEB: That's fine.

THE COURT: We'll do that.

MR. LOEB: There's still going to be some lead-up, Your Honor.

THE COURT: Maybe let's -- let's just wait. We're going to finish this in time by 2:30. Even if it takes 45 minutes, we'll do it, and then you'll have your opportunity. All right? So we'll wait.

Are there any other issues that we can deal with? I hope nobody is waiting to call.

MR. BLACK: I just need a five-minute break.

THE COURT: Let's do this. Take a break. As soon as he comes, can somebody knock on chambers so we'll know to come out and start right away. Thank you.

(Short recess taken.)

- - -

(Proceedings resumed after the short recess.)

THE COURT: All right. Thank you. Please be seated. Dr. Kirsch, thank you.

MR. LOEB: Your Honor, I don't believe that the witness has been sworn.

THE COURT: I already reminded him when he first got on the stand again that he remained under oath.

MR. LOEB: I missed him taking the oath.

THE COURT: I'm sorry? He took it three days

ago.

MR. LOEB: Okay. We have some binders to pass up. Your Honor, you should have three binders.

THE COURT: I do.

DIRECT EXAMINATION

BY MR. LOEB:

Q. Dr. Kirsch, thank you for coming back, and I apologize that your presentation is going to be a little bit discombobulated because of this disputes between the lawyers, but please bear with me, and if my questions don't make sense, I will just do my best.

So we're going to be starting -- one other thing I wanted to mention. Thank you very much for being here, sticking through trial and congratulations on your new grandson who was just born this morning?

A. Thank you.

Q. In any event, I'm going to start in the middle of your presentation at ten. All right. So what do you understand the purpose of the asserted patents, the inventions of the asserted patents to be?

A. The patents were aimed at devising compositions with improved properties, such as stability.

Q. And in your view, did the inventors succeed?

A. Yes, they did.

Q. And was the claimed invention ever commercialized?

A. **Yes, it was.**

Q. **And what is the commercial product that embodies the invention?**

A. **It's the reformulated Vasostrict.**

Q. **Okay. And did you consider whether the claimed pH of 3.7-3.9 was critical to vasopressin product stability?**

A. **Yes, I did.**

Q. **And what was the conclusion that you reached?**

A. **I concluded in -- I concluded as did the inventors that the claimed pH range of 3.7-3.9 was critical.**

Q. **All right. Now, did you review the prosecution of the applications that led to the asserted patents?**

A. **Yes, I did.**

Q. **All right. Did the inventors present any data supporting the criticality of the pH range of 3.7 to 3.9?**

A. **Yes, they did.**

Q. **All right. Now, I'd like to take you to the Vandse see declaration that Dr. Chyall --**

THE COURT: Can you stop? I'm sorry.

MR. LOEB: Yes.

THE COURT: I had thought Ms. Wu and Ms. Gaza were present in the courtroom, and I apologize. I had been informed that your expert was present and that's why I came in and we started.

MS. WU: Your Honor, I think we're okay. I just

wanted to give an update to Dr. Marais so he can understand what's happening here.

THE COURT: That's fine. Go ahead, have a seat. Let's wait before you do any other questioning.

MR. LOEB: Sorry, Your Honor. I didn't know what was going on behind me.

THE COURT: That's okay. All right. Thank you.

BY MR. LOEB:

Q. All right. Could we please have -- well, I would like to show you the Vandse declaration that Dr. Chyall testified about yesterday, which is DTX-007, and particularly, I think the page we want is 1883. And if you could look at that in your binder, please.

A. Could you give me the name or the number again.

Q. Yes. DTX-7.

A. Seven?

Q. Yes.

MR. LOEB: Can we have that up on the screen, please? Particularly 1883. Thank you.

BY MR. LOEB:

Q. Is this the Vandse declaration that Dr. Chyall testified about?

A. Yes, it is.

Q. Okay. And could you just page through and tell me how many pages the Vandse declaration is.

A. **So it appears to be 14 pages long.**

Q. **All right. Now, at the end of the Vandse declaration, which is pages 1893 through 1896, are those the stability study data that Dr. Chyall testified about?**

A. **Yes, that's correct.**

Q. **All right. These are the tables that he reproduced on some of the slides?**

A. **That's correct. Appendix 1 and 2, mm-hmm.**

Q. **All right. And then if you turn back and you look at the figures in Dr. Vandse's declaration, which I think is four?**

A. **Yes.**

Q. **Are those -- I'm not asking if they are the exact same copies, but are those the same figures in terms of content as the figures that Dr. Chyall showed yesterday?**

A. **Yes, that's correct.**

Q. **So all of that information was supplied in the 14-page document?**

A. **It was.**

Q. **Okay. Now, have you prepared a slide that -- we can take that down, please. Have you prepared a slide which illustrates what the inventors did, which is reported in the various declarations that we've been talking about?**

A. **Yes. Let's look at the next slide.**

Q. **All right. So what exactly in brief did the Vandse**

declaration and the following declarations show in terms of what was the experiment?

A. So they conducted experiments to look at pH optimization. They studied the reaction mixtures made in the range of 2.5 to -- a pH range 2.5 to 4.5 and they conducted studies at 25 degrees and 40 degrees for one month.

Q. Okay. And did the inventors provide their results to the Patent Office in a graphical form?

A. Yes, they did.

Q. Do you have a slide on that?

A. Yes. Let's go to the next slide.

Q. And what does that show?

A. So this shows the vasopressin decrease that, as a function of pH at 40 degrees, and the total impurity data at -- at -- as a function of pH again at 40 degrees and they identified from these data the region of optimal stability.

Q. And what is that region?

A. That region was 3.7 to 3.9.

Q. Okay. And one of the things that Dr. Chyall testified yesterday was that he thought that a four-week study was insufficient to demonstrate criticality. Do you agree with him?

A. No. This is not unusual at all. This is typical of

the way formulators would attempt to identify critical pH range and this is very typical in the art.

Q. Is there a reason that you showed the 40 degrees Centigrade data and not the 25-degree?

A. Well, in order to make distinctions between the effects of pH, you need to see enough degradation that you can, that you can make distinctions, and the 40-degree data provides that level of degradation.

Q. All right. Now, Dr. Chyall didn't show this figure here with the 40 degrees total impurities. Rather, he showed the same pH conditions, but at 25 degrees.

Do you think that that was appropriate?

A. Well, I don't think that the 25-degree data provided enough discrimination. There wasn't enough degradation that occurred at 25 degrees to actually understand the effects of pH on the degradation of vasopressin.

Q. And do you have a slide to illustrate, to compare those two?

A. Yes. Let's go to the next slide.

So, you know, this compares the data at 25 degrees, impurity data at 25 degrees, at 40 degrees, and I think the main point here is to notice the vertical axis scale. The vertical axis scale for the data at 25 degrees is a third of what it is at 40 degrees and this is because, you know, the magnitude of the, of the effects are not very

distinct at 25 degrees.

Q. Okay. And so just so the record is clear, you're comparing Figure 1 and Figure 2 from Dr. Vandse's declaration?

A. That's correct.

Q. And this slide -- I hit the wrong button. Doctor, this slide is an accurate representation of the separation except you've added some numbers bigger on top of it?

A. That's correct.

Q. Now, another criticism that Dr. Chyall had of the inventors' presentation of the data was in his view, they withheld the normalized data for impurities from the Patent Examiner.

So, first of all, what would the Patent Examiner have needed in order to determine the normalized impurities value?

A. So he would have needed the data that was provided to her in the appendices, so the initial values for total impurities and the final value of the total impurities.

Q. You're saying the Examiner had the data that would be necessary to determine the change of impurities over four weeks?

A. Yes, that's correct.

Q. Okay. And have you compared the total impurity graph that was presented to the Examiner to the same data that has

been normalized?

A. Yes. Let's take a look at the next slide.

So in this plot, what I'm showing is both the total impurity data -- let me see if I can get this to work.

Q. It's the red button?

A. Yes, I'm pressing the red button but I'm not seeing it on the slide.

THE COURT: I saw it.

THE WITNESS: Did you?

THE COURT: Yes. It's not that big.

THE WITNESS: That's all right.

THE COURT: You can say blue and orange. I will figure it out.

THE WITNESS: Thank you.

The total impurities are the blue curve and the change in impurities are the red or orange curve and basically, they're parallel. So I mean, they show the same region of maximum stability whether you look at the total impurities four weeks, 40 degrees, or you look at the change in impurities, four weeks, 40 degrees.

BY MR. LOEB:

Q. So would a person of skill in the art evaluating the normalized information at 40 degrees come to a different conclusion than if that person of skill in the art was

evaluating the non-normalized total impurity data?

A. **No. They would come to the same conclusion.**

Q. **All right. Was the data presented in a false or misleading manner to the Patent Office?**

A. **No, it wasn't.**

Q. **Now, Dr. Chyall also said that the level of impurities in the vasopressin which was used in the, say the two arms of the pH experiments was different, and that this difference would make the results unreliable. What's your response?**

A. **Could you repeat the question? I'm sorry.**

Q. **Sure. If you recall, Dr. Chyall had a slide that showed that the levels of impurities that the arm of the experiment that was done from 2.5 to 3.5 were higher than the impurities at the beginning for the other arm of the experiment, which was 3.5 to 4.5. And my question is: Do you think that difference makes the result unreliable?**

A. **No, it doesn't. I mean, there was adequate time dependent changes. That is to say stability changes that occurred at 40 degrees -- 40 degrees and four weeks to overcome any differences that there might have been in the starting material.**

So you would have come to the same conclusion whether you used the normalized -- not normalized in whether you took into account that difference.

Q. **Okay. Does the normalized data which you indicated in blue on your figure account for that difference in initial impurities that Dr. Chyall was talking about?**

A. **Yes, that's correct.**

Q. **All right. Are the data --**

A. **Excuse me. I may have misspoken. The change. Was that your question, that the change in impurities, which is red?**

Q. **Yes. I was the one who made the mistake?**

A. **Thank you.**

Q. **I identified them backwards?**

A. **Yes.**

Q. **So do you understand what I was trying to say?**

A. **Yes. I mean, the normalized circles, normalized data would take care of that issue.**

Q. **Okay. And are the data from the Kannan and Vandse declarations discussed in the asserted patents?**

A. **Yes, they are. They're presented as examples in the patent. Let's go to the next slide.**

Q. **Sorry. This one?**

A. **Yes. So in the asserted patent, the example 9, 10 and 11 are the -- are the Vandse declaration data, or declaration data.**

Q. **All right. And are the figures, the graphs that we've been looking at and Dr. Chyall talked about, are those**

actually in the patent specifications of the '785 and '209?
A. Yes.
Q. Patents?
A. Yes. It's highlighted in the text, the Figures 11, 12, 13 and 14 were also included in the -- in the specification.
Q. And what about the -- the additional figures, 15 through 18? Are those relevant also?
A. Yes. That's correct. There's additional Figures 15, 16, 17 and 18.
Q. And did you find any statements Par made during prosecution of the '785 and '209 patents that relate to the criticality of the pH range?
A. Yes. Let's go to the next slide.
So this statement, which is highlighted here, appears in both patents. I'm sorry. In the -- in the response to office action for both patents and it says, the present specification establishes the criticality of pH 3.7 to 3.9 and that was at PTX-843 for the '209 patent and PTX-844 for the -- for the '785 patent, both of them from a June 2017 office action response.
Q. Okay. And in that office action response was there any relevant graphical information?
A. Yes. They presented the total impurity data at 40 degrees, which showed the pH minimum region.

Q. **All right. Now, have you performed any independent analysis to confirm the inventor's conclusions regarding the criticality of pH 3.7 to 3.9?**

A. **Yes, I did.**

Q. **So before we get to what you did, do you have any experience in performing statistical analyses to evaluate peptides and stability to make formulations?**

A. **Yes, of course. This is, you know, a key part of my -- my activities in studying the stability and degradation kinetics of peptides, which I've been doing over my professional career and I've had courses in -- in statistics at the undergraduate and graduate level.**

I've worked with statisticians over the years in industrial sciences and at the commission, so I've had a fair level of experience in applying statistical methods to stability and drug degradation data.

Q. **And in your career as an academic scientist, did you ever use the statistical software that scientists in your field used to analyze stability data?**

A. **Yes, mm-hmm.**

Q. **What's that called?**

A. **Well, I mean, they used different programs, but JMP is one of the ones. This is a program from the SAS Institute, which is very commonly used. You see it sometimes in the FDA guidance, you see output from that.**

Q. **Now, I would like to get back to the analysis that you did in this case. Could you describe that, please?**

A. **Sure. So let's go to the next slide.**

So what I did was to take a -- to calculate the total or consider the total impurity appearance rate, which is the difference between two measured values, the difference between the total -- the initial total impurity and the -- and total impurity at one month and I did this using the 40-degree data.

Q. **The data from where, Doctor?**

A. **The data from the -- from the declaration. The data was presented in the patent from the experiments that the inventors conducted.**

So this is, you know, essentially the normalized, so-called normalized total impurity data.

One of the important things to note about this kind of data is that it's actually -- the total impurity measurements are the summation of many different peaks.

All of the individual impurity values are included in that, in that measurement for each total impurity measurement. So, and then what we do is we look at the difference between the initial -- the value at four weeks.

Q. **I'm sorry to interrupt.**

A. **No. Go ahead.**

Q. **Is this what Dr. Chyall was referring to as normalized impurity data?**

A. **Yes, that's correct.**

Q. **Okay. So could you explain your analysis?**

A. **Sure. So let's go to the next slide. So this is sort of a hypothetical example. Let's suppose that I have determined the total impurity appearance rate at different pH values, so I have these values and I want to compare them at pH A, B and C, and, you know, the question that I have is, are these, you know, I can see that numerically, they're different, but the question is, are they -- are they different?**

Can I -- can I actually say that they are different? And so what I need to do is in some way estimate the variability with those -- with those values.

So let's go to the next slide.

So the issue then is if I can determine the variability in some way, then I can get a range of values which would -- which would represent the -- the -- which would represent both the estimated value and the variability that's associated with that estimated value.

And then what I would do would be to look to see whether or not there is overlap between the -- the intervals that describe that -- those estimated values.

So, for example, if I'm comparing the value I

got at pH A to the value I got at pH C, I can see that the -- the intervals do not overlap and therefore, those differences must be greater than the -- than simply the measurement differences.

On the other hand, if I compare the values I got at pH A versus the values I got at pH B, I can see that they do overlap and therefore I can't make a conclusion as to whether or not those values are different.

So the issue then becomes how you estimate the variability associated with the total impurity appearance rate.

Q. How did you do that?

A. Let's go to the next slide. So what I needed to do was to find some estimates of the variability associated with the individual impurity peaks, because remember, the total impurity measurements are a summation of the individual impurity peak measurement.

So I was able to find the technical report, 13033-R, which is a product development report, which described the analytical methods used to measure impurities, and from that in Table 1.1 or 1-1, there was some useful information.

On the left-hand side we can see there is listed a number of related substances that -- for vasopressin impurities that are, that are identified in the, in the

samples.

And in the far right-hand column, we can see that there are estimates of the standard deviations associated with these of these impurity values. These were estimated from replicated estimates in what the investigators took.

And what we can see -- so these, these standard deviation values are estimates of the variability associated with each of the peaks, impurity peaks, and what you can see is that those values range from 0.001 to 0.004. So that gives me a pretty good idea of the type of variability that's associated again with the individual impurity peaks.

Q. All right. May I just interrupt you for a second for the record here? You've been looking at Table 1.1, which is at the Bates number ending in 698 from DTX-1143?

A. Correct.

Q. Okay. And are these data specific for the Par measurement technique for impurities?

A. That's correct. So --

Q. In my effort to make the record clear, I made the record unclear. I apologize for that. Page 690 of DTX-1143; is that right?

A. Yes.

Q. Okay. So once you found this information, what did you do with it?

A. **So let's go to the next slide then.**

So, again, we're looking at the change in total impurities with time or the total impurity appearance rate. We have -- I made calculations for each of the pH values that were studied and what we need is some estimate of the variability of those values.

So to do that, I estimated the standard deviation for the total impurity appearance rate by considering all of the components that went into that calculation and to do this, I was -- I assumed that there were 25 individual impurity peaks, which is the most that I have seen for any of the measurements that are -- have been reported that I've seen. And I also used a standard deviation value of 0.01, which is twice, over twice the value that I -- that we saw in the previous page for any of the individual impurity peaks.

So I was pretty robust in terms of estimating the variability associated and the number of individual impurity peaks.

From that, from those estimates, then I could calculate a standard deviation value for the total impurity appearance rate, which I estimated to be 0.07, and I could then use that value to calculate by standard methods the 95 percent confidence limit for the total impurity appearance rate at each pH, and those values are the -- the

confidence limits are given by the estimated value for the total impurity appearance rate, plus or minus 0.14.

So remember that I'm looking at whether the total impurity appearance rate value at each pH are different or not, so they have to be significant -- they have to be enough different from interval, it has to be no overlap in the interval, so the critical value for looking for a difference turns out to be 0.28 percent. In other words, if I found differences between the total impurity appearance rate between two pH experiments or two pH conditions that was greater than 0.28, then we could say that these are -- these are significantly different.

Q. So before you go on --

A. Sure.

Q. -- no, actually, I withdraw that. Did you apply this approach to the data which is found in the Vandse declaration?

A. Yes, that's correct.

Q. And what did you find?

A. Okay. So let's go to the next slide.

And what we -- what I'm showing in this slide is the results that were obtained at every pH that was studied by the investigators.

In the left-hand column is the pH condition. In the second column is the total impurity appearance rate

value, which is titled -- entitled there "Change in impurities at 40 degrees," and so this represents the estimated values for the total impurity appearance rate at each pH plus the estimated confidence limit.

And so then the issue becomes to be able to compare these values. So I did that by -- let's do a comparison and I will try to explain how that works.

So if we look at the value for the total impurity appearance rate in column 2 at pH 3.8, 0.88, and we compare that to the value at 3.6, which is 1.64, we can calculate the difference between those two total impurity appearance rate value, and if you look in column 3, then that difference is 0.76.

Now, if that value, the difference is greater than the critical value of 0.28, then in the sixth column, I've indicated that that is significantly different with -- by saying yes.

Q. Dr. Kirsch, I think you counted wrong.

A. One, two, three, four, five, fifth column.

Q. Okay. Go ahead, please.

A. Yes. So I did that for each and every condition that was studied, and what you can see is that for all the pH values less than 3.7, they were different than the value that was obtained at pH of 3.8. So that's what that's all about.

And then I did the same -- used the same process to compare the values at three point -- the value at 3.7 to the rest of the value that -- the rest of the pH conditions.

Q. **What did you find -- for the comparison between pH 3.7 to the values for the pHs 2.5 to 3.6?**

A. **Once again, those were all beyond the critical value of 0.28 and therefore, they were statistically different than the -- than the value at 3.7.**

Q. **Okay. What did you find for this -- in comparing the values of 3.7 to the values between 4.0 and 4.5?**

A. **So most -- generally, they were different. There are a few there that were not different.**

Q. **Okay. So to be clear, we're looking at the fourth column?**

A. **Yes, that's correct.**

Q. **All right. And I failed to mention, this is PDX-6-23. I'm just talking about the numbered slide.**

A. **Yes.**

Q. **Okay. What happened when you compared the values at 3.9, the value at 3.9 in this one, which is .7 to the values in the range of 2.5 to 3.6?**

A. **So they were all different as well and the values above the claimed range were different for the most part. There was -- there was not a difference seen at pH four.**

So -- and certainly --

Q. **I'm sorry. I was asking about between 2.5 and 3.6.**

A. **Yes.**

Q. **Compared to 3.9. What did you find?**

A. **They were all different.**

Q. **Okay. And then what happened when you compared 3.9 to 4.0 to 4.5?**

A. **So they were different for the most part except for the value at 4.0.**

Q. **Okay. So taking all of the comparisons between each of 3.7 and all of the other pH values that were tested, and 3.8 versus all the other values that were tested and 3.9 versus all the other values that are tested, what's your overall conclusion concerning whether there's a statistically significant difference between the range of 3.7 to 3.9 and the broader range of 2.5 to 4.5?**

A. **So overall, the values at 3.7, 3.8, 3.9 represent are the values of minimum instability or maximum stability in terms of the total impurity appearance rate.**

Q. **All right. Was your conclusion, statistical analysis that you performed, consistent or inconsistent with what the inventors concluded when they looked at the same data?**

A. **It was consistent with what the inventors found.**

Q. **Now, would you expect there to be a stability advantage for a vasopressin formulation within the claim pH 3.7 to 3.9 range compared with Vasopressin's formulations**

with a pH outside of the claimed range?

A. Yes. I would expect that there is greater stability for the values -- for preparations within 3.7 to 3.9 and outside.

Q. Okay. Now, given this analysis, do you agree with Dr. Chyall that the data in the declarations did not justify the inventors' conclusion?

A. No, I don't agree. I think it did justify the inventors' conclusion.

Q. All right. Now, you prepared reports that responded to Amneal's expert; right?

A. Correct.

Q. So you read all the reports of Amneal's expert in the case?

A. Yes, I did.

Q. And did you -- first of all, did you see in any report that Dr. Marais provided any criticism at all of your statistical analysis, which we're just looking at now?

A. No, I didn't.

Q. All right. Now, did Dr. Marais do his own analysis?

A. Yes, he did.

Q. All right. Now, was Dr. Marais' analysis the type of statistical analysis that you use in the discharge of your research?

A. Yes. It's consistent with -- with the type of

analysis that I would do as well.

Q. All right. And what did Dr. Marais' statistical analysis show?

A. So let's go to the next slide.

Q. The one after I think because I'm thrown for a loop here?

A. Now, this is an excerpt from Dr. Marais' opening report and he did find some evidence of statistically significant difference when he compared the data for pH 3.7 to 3.9 compared to data for pH 3.6.

To do his analysis, he needed to go outside of the -- the data that was presented in the -- in the declaration, so he also used some additional data from a different set of experiments.

Q. And what kind of analysis -- what's it called, the kind of analysis that Dr. Marais did?

A. Initially, he did a linear regression analysis and estimated slope and compared those with the appropriate test. And you can see that in the row on the bottom, which is highlighted, he found a difference when the combined effect of intercept and slope, he saw that that was statistically different.

You can tell that by looking at the right-hand column where the P values, typically, the P values are less than 0.05. That is a statistically significant difference,

and in this case, the P value was 0.042.

Q. And just for context here, if we go back to your table, that is on PDX-623, could you explain where on here it relates the same comparison that Dr. Marais did? Which pHs was he comparing? Where would they appear on here?

A. Okay. He was comparing the claimed range to the -- to one pH value. That's the value at 3.6. So he didn't look at all of the -- all of the pH, the data pertaining to all of the pH values, but he just chose one value, 3.6, and compared that to the range of 3.7 to 3.9.

Q. All right. If I understand correctly, more -- if I understand you correctly, what you are saying is Dr. Marais compared 3.6 to the aggregate of 3.7 to 3.9?

A. That's my understanding.

Q. Did Dr. Marais do any comparisons of any other values, like 2.5 to 3.5?

A. No.

Q. Did he do from 4.0 to 4.5?

A. No.

Q. And did Dr. Marais provide any opinions about whether it's appropriate to -- I mean, scientifically, as a stability or formulation scientist, whether it was appropriate to combine the data that he did?

A. I don't recall anything in his report that discussed

that.

Q. All right. Okay. So obviously, since I'm taking it out of order, I want to get every question?

THE COURT: That's fine. I also don't need that we need to get into -- I didn't think we were getting into his opinions, just the statistical analysis. You know, I will try to be fair.

MR. LOEB: Understood.

THE COURT: I mean, they are not presenting him as a rebuttal, at least not yet, to all of this. The fact they are not presenting him as a rebuttal, you're free to argue that as opposed to presenting testimony that hasn't been challenged.

MR. LOEB: Fair enough. At this point I would like to invite Dr. Kirsch, or if they want to do their cross-examination now.

THE COURT: That was it? All right.

MR. LOEB: That was it.

THE COURT: All right. Well, I will tell you what. Do you want to take a break? Do you want to present? Do you want to cross? It's up to you what you want to do.

MS. WU: I would ask us to take a break, Your Honor. That way I can also caucus with Eagle's counsel to make sure we're covering the scope that Mr. Loeb and Dr.

Kirsch just presented.

THE COURT: All right.

MR. HALES: I want to just clarify. What is the expectation? Does that mean if we break, there's going to be cross on this point?

THE COURT: Only on this point. My attitude is, I'm open to suggestions. I'm trying to be fair. So I'm thinking, and I'm trying to get through this. Right?

MR. HALES: Understood.

THE COURT: And I mean, this was a tiny bit of testimony. You can have the option of crossing on this particular point. By this particular point, I mean the last five minutes that was adduced, I think, and that's it, nothing else. It has to do with the analysis that Dr. Marais raised and that's it.

Now, you could also decide to not cross on that and save it all. You could decide to cross on that and then quickly call Dr. Marais. You could decide not to cross and call Dr. Marais. I think even if we took a half-hour break and got back at 1:45, you would have 45 minutes. Do you need more than that? I wouldn't think so.

So do you want to take the half-hour? We'll start at 1:45 sharp? Do you want to caucus real quickly?

MR. HALES: No, no. I want just actually want to clarify things. Where we ended was not even the Marais

point. I think we had already gone past the point about Marais.

THE COURT: I think we ended right at Marais. What am I missing?

MS. WU: It is with Marais. Your Honor, just so I'm clear, there was Dr. Kirsch's statistical analysis and one slide of Dr. Marais. It's just not the Dr. Marais slide. It's the statistical package where we can cross now. Is that right?

MR. HALES: Maybe to clarify, can you pull up the last -- I mean, I thought that was --

MR. LOEB: So --

THE COURT: I will tell you what, why don't you go ahead and step out.

(Witness excused.)

THE COURT: Dr. Marais, why don't you step out, too.

MR. LOEB: The only reason why I referred back to this is it had the range.

THE COURT: And take your time to decide what you want to do. All right.

MS. WU: Your Honor, I think there's a little more caucusing we have to do. I think a half-an-hour break would be appreciated.

THE COURT: He has to leave at 2:30.

MS. WU: Yes, we're mindful of that.

THE COURT: You have to give them a little bit of cross. They have to cross him, too.

MS. WU: Yes. Should we maybe split the difference and do a 20-minute break then?

THE COURT: I will do whatever you want. I can work throughout lunch, but, you know --

MS. WU: Just a few minutes to make sure there's plenty of time.

MR. BLACK: Redirect will be very brief as long as she stays within the scope of what has been offered.

THE COURT: Redirect.

MR. BLACK: I'm sorry. The direct. I don't know where we are anymore. This is so upside down, I'm sorry.

THE COURT: Of course, it is. That's what happens at bench trials.

MR. BLACK: The cross of Marais will be very brief so long as he stays within the opinion --

THE COURT: Here's what we'll do. You know, we're close to the finish line. You all can celebrate when you're finished. We're going to come back at 1:30 with a decision as to what we're doing. All right?

(Short recess taken.)

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(Proceedings resumed after the short recess.)

THE COURT: All right. All right. Please be seated.

Ms. Wu, what do you want to do?

MS. WU: Your Honor, I really appreciate all the options and the fairness being exercised here. I think after discussing with my colleague, I think we can just cross everything at the end.

THE COURT: Okay.

MS. WU: And we do not plan to have Dr. Marais come, and so I think if it's okay with you, Your Honor, that he be excused at least for now. Again, we have the outstanding Amneal trial for the proposed products in the future.

THE COURT: In the future. That sounds right.

MR. BLACK: No objection, Your Honor.

THE COURT: Okay. Thank you, Dr. Marais.

DR. MARAIS: Thank you, Your Honor.

THE COURT: All right. Now, I leave it to you all since I've deprived you of lunch. I'm ready to go, but, you know, you guys tell me.

MR. LOEB: Well, I wouldn't mind having a little lunch.

MR. BLACK: We could -- yes. We had ten minutes.

THE COURT: I will give you -- my point is, look, what's left?

MR. BLACK: This.

THE COURT: This is it?

MR. BLACK: Yes, this is it.

THE COURT: What do you want for lunch?

MR. HALES: I think another 20 minutes.

THE COURT: I will give you at least 20.

MR. BLACK: 27 minutes, Your Honor.

THE COURT: The question is: Do you want more? When we finish up with him, I'm going to have some questions for you all.

MR. BLACK: Okay.

THE COURT: Do you want to do that? Do you want to break for half-an-hour, everybody have lunch, relax and come back.

Okay. Thanks. Let's break. We'll be back at 2:00.

(Luncheon recess taken.)

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Afternoon Session, 2:02 p.m.

THE COURT: All right. Please be seated. All right. Give me one second. Okay. Thank you.

BY MR. LOEB:

Q. **Welcome back, Dr. Kirsch. For the Court's benefit as**

well as yours, I just want to give a little context as to where we are and what my roadmap is. I would like to finish discussing with your opinions relating to criticality and then what I'm going to do is go back to the beginning of the presentation as Dr. Kirsch and I had intended to and obviously I won't do criticality again, but skip it.

Okay. Here we are. Dr. Kirsch, did you find any other real-world data, I'm talking now beyond the data that Par presented to the Patent Office that related or assisted you to make your conclusions concerning criticality?

A. Yes, I did.

Q. And did you look at the stability data for the registration batches of original Vasostrict and compare those to reformulated Vasostrict?

A. Yes, I did. I did that.

Q. All right. Did you prepare a slide on that?

A. I did.

Q. If I can find it. Actually, I think we should look at a document before we do that. Could you look in your binder at DTX-53 and tell me what that is? I think that the DTX exhibit binders are in -- that the DTX exhibits are in Volume 2?

A. Okay.

Q. All right. What is this document?

A. You said 53; is that correct?
Q. That's right?
A. Yes. So this is a product development technical report on Vasostrict, on the original Vasostrict.
Q. All right. Is this one of the documents that you looked at?
A. Yes, it is.
Q. Okay. And if you could please look at PTX-411, so that would be in the other binder.
A. Right. So this is a collection of stability results for registration batches and I think there's -- for reformulated Vasostrict and I think there's some original Vasostrict up there as well.
Q. Okay. Now, how does the stability data, the original Vasostrict registration batches, compare to the stability data for reformulated Vasostrict registration batches?
A. There are differences. We can look at the slide where I captured some of those.

So what we're seeing here is a -- some excerpts from those two documents that we just looked at. On the top are data from original Vasostrict registration batches. These were for the three registration batches and this is the 12-month, or the change in, in the total impurity values at 12 months, 25 degrees.

Q. Okay. And what did you find?

A. So what I found was -- well, first of all, all of the pH values that were collected for these registration batches were within the 3.4 to 3.6 range. I think that there may have been one value which was at 3.2 and that's that asterisk there.

But in any case, what I'm showing here is the average increase in total impurities, which was the average, which is highlighted in yellow, was 45 percent -- 4.5 percent. Excuse me.

And if we look at the bottom of this collection of data, then these are the reformulated Vasostrict registration batches, and for these registration batches, all of the pH values from stability data fell within the range 3.7 to 3.9, so they fell within the claimed range and the percent increase in total impurities was 3.5 percent, so there was a 22 percent reduction in the level of impurities in the reformulated Vasostrict as compared to original Vasostrict.

Q. Now, what would a person of ordinary skill in the art -- well, let me rephrase the question. Would a POSA consider a 22-percent reduction in the rate of formation of total impurities for 12 months at 25 degrees to be a meaningful or a not meaningful improvement in stability?

A. Well, they would see it as meaningful and also with significance, because the variability associated with the

individual values that are reported there is very small. So it's very clear that those are, those are real differences.

Q. Okay. I just want to ask you about a little detail here. Earlier when we were talking about the data in the patent, you testified that you thought that the impurity measurements that were taken at 40 degrees were more reliable than the ones that were 25 degrees.

Why is it that you're looking at the 25 degree data here.

A. Well, now for these data, the studies have been conducted over a sufficiently long period of time that you can see the differences in the rate of appearance of the total impurities.

Q. So what is the significance of the data and the analysis that is set forth on PDX-626 to the criticality of the claimed pH range?

A. So this is, you know, this is supportive. It indicates that the pH factor manifested itself in the reformulated Vasostrict batches and we see an improvement in stability.

Q. Now, did you hear the testimony of inventors Kenney and Kannan that their data showed that reformulated Vasostrict had a four-month increase in room temperature shelf life as compared to original Vasostrict?

A. **Yes.**

Q. **And would a POSA consider a four-month increase in room temperature shelf life a meaningful or not meaningful improvement in stability?**

A. **Well, they would, they would see that as a meaningful improvement.**

Q. **All right. Now, defendants' experts testified that original Vasostrict and reformulated Vasostrict have the same approved shelf life conditions. Does that impact your conclusion?**

A. **No. The decisions about dating are -- are more complicated than are not about criticality per se. So, you know, they're based on other decisions other than simply the rate of change in those samples.**

Q. **Dr. Chyall argued that the impurity specifications are the same between reformulated Vasostrict and original Vasostrict. How does that affect your opinion?**

A. **It's the same thing. The decisions about those limits are -- are outside of scientific assessment of criticality. I mean, they're more regulatory decisions and corporate decisions.**

Q. **Okay. And have you seen any data from Eagle which bears on your opinion concerning the criticality of the claimed pH ranges?**

A. **Yes. Let's look at the next slide. So this is**

basically the same type of data. This compares the -- the registration batches of Eagle SVA2 and 3, all of which had a pH within the range of 3.4 to 3.6 and what we're showing -- what I'm showing here again is the same comparison where we're looking at the increase in total impurities, 12 months, 25 degrees, and here you can see that the increase for the Eagle registration batches was 5.5 percent and, once again, we've seen the data for the reformulated Vasostrict registration batches, which practice the pH limits of the, of the patent. They all fell within 3.7 to 3.9 and there, the average increase was 3.5 percent, so now we're seeing 36 percent reduction in -- in the appearance of those impurities.

Q. Is 36 percent reduction in the accumulation of impurities over 12 months at room temperature a meaningful or a not meaningful change?

A. It's a meaningful change.

Q. All right. Now, Dr. Park testified that Eagle's ANDA product is the same as original Vasostrict. Do you agree?

A. No, I don't. There are differences in the stability actually of Eagle's product and -- and original Vasostrict. You know, they are -- they're not the same.

Q. Okay. Just so we cover it, did you get the Eagle SVA2 stability data from DTX-125?

A. **Yes.**

Q. **And did you get the Eagle SVA3 stability data from DTX-128?**

A. **That's correct.**

Q. **Now, Dr. Chyall implied that the comparisons that you've done here between reformulated Vasostrict, original Vasostrict and Eagle's' product -- these are not his words, but I'm trying to summarize, an apple-to-apple kind of comparison and therefore you shouldn't -- it shouldn't be meaningful.**

Do you agree with that?

A. **No, I don't agree with that.**

Q. **Why not?**

A. **I mean, I've looked at the -- their compositions of those -- of these products and, you know, the differences are, in my view are not -- are not significant relative to the differences in pH.**

The pH effect is the predominant effect. I mean, if you look, for instance, they both contain acetate and the only real difference in composition is the chlorobutanol and it seems unlikely to me that Eagle would use a preservative that it could adversely affect the stability. That doesn't seem to be reasonable either.

Q. **Did you analyze any additional data from Eagle and Par to try to confirm whether the pH of 3.7 to 3.9 range was**

critical?

A. Yes, I did.

Q. What data did you look at, what did you find?

A. Well, I looked at all of the available room temperature 12-month data for Par's two products, original Vasostrict and reformulated Vasostrict, and I -- and I also looked at Eagle's data and I found statistically significant differences between both the rate of vasopressin lost and the appearance of impurities.

Q. Now, Dr. Chyall opined that a different -- difference in kind is required to prove criticality. What's your reaction to that?

A. Well, in my view, that is not relevant to drug stability processes. You know, in peptide degradation, we have the combination of multiple parallel pathways degradation, all of which have their pH dependence, and so it is the combined effect of those different pathways that gives rise to an optimal pH range.

Outside that pH range, those pathways are still in effect, I mean, but they are -- collectively provide for a less stable formulation.

Q. All right. Now, would it be possible to show Chyall slide DDX-431? Sorry. I didn't know you had it up there.

Do you remember Dr. Chyall pointed to the fact

that the release specification for reformulated Vasostrict is broader than the 3.7 to 3.9 range and therefore in his view, that 3.7 to 3.9 range can't be critical?

A. Yes, I recall that.

Q. Have you prepared a slide in response to that?

A. Yes. Let's take a look at the next slide.

Q. I think that's number 28. I'm headed in the wrong direction again. What's your opinion?

A. Well, you know, there is data that I've looked at that demonstrates those differences. I think that, you know, he's conflating the -- the FDA specifications with the notion of criticality.

I don't think that the FDA specifications are a reflection of the issues of criticality and Dr. Chyall hasn't shown any data of reformulated Vasostrict outside the 3.7 to 3.9 range. The data that we looked at, the data that we just looked at was all within that 3.7 to 3.9 range.

Q. Okay. Have you prepared a slide that sort of summarizes your disagreement with Dr. Chyall?

A. Yes. Let's take a look at the next slide then.

Q. Sorry. They're all out of order now. Please explain.

A. Well, I think in the first place, he has put an over emphasis, if you will, on the 25-degree data. We saw a lot of that. But, again, the changes that were seen in the

25-degree data really weren't enough to, to make conclusions in and of themselves.

You know, the real-world data is what was -- analysis was not complete, and then my statistical analysis that I had to demonstrate the differences and the -- and the claimed range is, in fact, the range of that stability.

Q. Does your opinion concerning the criticality of 3.7 to 3.9 apply only to the specific formulations that were tested and you compared?

A. No. The studies that were done to look at pH were done in acetate buffer. The inventors also reported on the effect of acetate buffer, if you will, on degradation. They found that it had no effect on degradation. That was actually presented in one of the examples in the patent, I think example ten as I recall. So the effects that they are looking at are pH effects. They demonstrate the pH criticality.

Q. All right. So at this point I'm not going to ask you any more questions about criticality, but I do want to start at the beginning of your presentation. Could we just go back to slide number 1, please.

So with respect to defendants' prior art attacks, first, on Wednesday you discussed how a POSA would understand when the pH and impurity limitations must be measured according to the claims.

Just as a reminder, when must the pH and impurity limitations be measured?

A. **So they need to be measured within the shelf life and they need to be -- need to show that they were both met concurrently. The next slide I think will illustrate this.**

So for both patents, the '785 and '209 patent, the formulation limitation of pH range 3.7 to 3.9 and concurrently, the impurity limitations of .9 to 1.7 percent for specified impurities need to be met and then there were additional clinical claims that also need to be met for the '209 patent.

Q. **What about the dependent claims of both the '785 and '209 patents?**

A. **Yes. So they would need to be met concurrently with the elements of the, of claim 1, the independent claim.**

Q. **All right. Have you prepared a summary of whether original Vasostrict meets the claim requirement?**

A. **Yes. Yes, I have. So neither of the two asserted pieces of prior art meet the pH limitation and the impurity limitation concurrently. Not the original Vasostrict product and not the April 2014 label either.**

Q. **Have you evaluated the state of the art at the priority date of the asserted patents, which is February 7th, 2017?**

A. **Yes.**

Q. **What was known in the prior art about the stability of vasopressin products?**

A. **Well, vasopressin products were known to be stable and safe and efficacious.**

Q. **During their testimony, did any of the defendants' experts say otherwise?**

A. **No.**

Q. **Was the stability of original Vasostrict or Pitressin a recognized problem to be solved in the prior art?**

A. **No, it wasn't. It was believed that the pH had been optimized.**

Q. **Were the impurity levels within vasopressin products considered a concern in prior art?**

A. **No. The impurities were not known in the prior art.**

Q. **Did the prior art teach anything about the possible pH for vasopressin?**

A. **Yes. Let's go to the next slide. So the FDA has made a couple of reports, review reports. The FDA biopharmaceutics review, PTX-146 and the FDA chemistry review, PTX-309, which made clear that the optimal range for stability was 3.4 to 3.6. Original Vasostrict had limits of 3.4 to 3.6. That's found in the May 2015 Vasostrict label, DTX-132.**

And, additionally, there is the Bi study, DTX-173, and also the FDA pharmaceutical -- well, the

Pitressin pH, what was known about the Pitressin pH, which was 3.6, and that was shown in the FDA Biopharmaceutics Review, PTX-146.

Q. All right. So of all the relevant prior art that you reviewed, did any specifically point towards the 3.7 to 3.9 range?

A. No, none of them.

Q. All right. And I'd like to turn to the Bi 2000 reference. Have you prepared a slide about that?

A. Yes. Let's take a look at the next slide.

Q. Where is that shown?

A. So this is an excerpt from the Bi 2000 report, which was a study conducted on the instability of vasopressin as measured by a loss of vasopressin, and this is a typical pH rate profile that we might see in this type of a paper, so we're plotting the rate constant against pH, and what you can see is that in Bi's study, he found that the minimum rate of degradation occurred at a pH of 3.35, which rounds to a pH of 3.4.

So this is what he found. And he also looked at a study within the claimed range of 3.66, which is -- what rounds again to 3.7 and found less stable product in the claimed range.

Q. Okay. So are we looking at Figure 2 from DTX-173?

A. That's correct. And it's the pH rate profile for the

degradation of AVP. AVP is arginine vasopressin.

Q. Now, does the text of Bi 2000 comment on Figure 2?

A. Yes. It states that Figure 2 indicates that AVP is the most stable at pH 3.35 among pH values tested and its degradation rate is highly pH dependent.

Q. In view of Bi 2000, what would a POSA have expected the results of increasing the pH of vasopressin formulations above pH 3.4 towards the claimed range?

A. Well, they would have seen the data that Bi presents that vasopressin is less stable, certainly at a pH of 3.66, which is shown.

Q. Would a POSA have found Bi 2000 teachings relevant to the understanding of what the optimal pH was for vasopressin formulation generally? In other words, more than just for the formulation that it talks about?

A. Yes. He's showing a pH effect and actually, you know, he conducted his studies in a different buffer and also did a study to determine whether or not the buffer had an effect and he found that the buffer did not have effect on the rate, and so what he said was we're looking at a pH effect.

Q. Looking at Figure 2, would a POSA understand anything about the statistical significance of Bi's data?

A. Well, Bi also presented his data with error bars, so he has error bars around his rate constant estimates, and

you can see that those error, those data are widely spaced apart and the error bars indicate that these are different values that he obtained.

Q. Did any of defendants' experts comment on Bi 2000 to your recollection?

A. I don't recall.

Q. Okay. Now, I would like to look at two of the references that you already mentioned. First the biopharmaceutics review, and I'd actually like you to look in your binder at this one. It's PTX-146.

A. Okay.

Q. And could you just explain what PTX-146 is by just paging through the first couple pages of it?

A. Sure. So this is -- this is from the center of drug evaluation and research at the FDA. This is a review of the original Vasostrict NDA.

Q. Okay. And was this biopharmaceutics review on original Vasostrict published before the priority date of the asserted patent?

A. Yes, it was.

Q. Okay. And I'd like now to look at PTX-309 in your binder, the next tab, and if you could explain what that is.

A. So this is another review document from the center of drug evaluation and research. This is from the chemistry

section, so this would be part of the chemistry review of original Vasostrict NDA.

Q. And was the chemistry review published before the priority date?

A. Yes, it was.

Q. The asserted patent, just to be clear?

A. Yes.

Q. Okay. And could you just explain briefly is the purpose of these FDA documents?

A. The purpose is to summarize their observation about the review of that NDA from the chemistry and manufacturing section and also from the biopharmaceutics section.

Q. Have you prepared a slide which has anything from those documents which is relevant to the question of what ordinary skilled artisans would have understood the preferred range for pH for vasopressin to be?

A. Yes. Let's go to the next slide.

Q. So we're at PDX6-7 now. So what do they say?

A. So from the FDA biopharmaceutics review, they stated that the pH of the formulation is critical because at pH's below 3.4 and above 3.6, degradation of vasopressin accelerates, with the degradation rate increasing as the pH deviates further from the pH 3.4 to 3.6 range.

Q. And what did the chemistry review say?

A. The chemistry review has some similar comments in the

chemistry re-review they said the pH is a critical parameter in the Pitressin formulation, in the pH range 3.4 to 3.6 vasopressin acid salt is relatively stable in water, and degradation accelerates at the pH that's above and below this range.

Q. So what did these two published FDA reviews teach a POSA about the optimal pH for vasopressin?

A. Well, they make it clear that the optimal pH for vasopressin is 3.4 to 3.6.

Q. All right. And have you prepared a slide to summarize what a POSA would understand about the optimal pH of vasopressin?

A. Yes. Let's take a look at the next slide. This is essentially the same slide we looked at before, but with the FDA's comments that the optimal pH is 3.4 to 3.6 and degradation accelerates above and below that range, which is also what a person of ordinary skill would glean from original -- from an original Vasostrict range and also the Bi article and the Pitressin pH.

Q. Based on the teachings of the prior art as a whole, what would a POSA have expected the stability of vasopressin formulation with a pH of 3.7 to 3.9 to be?

A. Well, they would have anticipated that it would be less stable in the pH range 3.7 to 3.9.

Q. All right. Did you find any more teachings in the

prior art disclosing pH's for vasopressin products?
A. Yes. There were additional pH ranges. Mainly, the 2.5 to 4.5 ranges that were -- that were seen in a number of labels and documents, the PPC label, DTX-136. The American Regent label, DTX-246.
Q. Dr. Kirsch, just in the interests of time, I'm going to have you skip over the remainder of those and we'll continue. But did you find any other pH ranges that were any different than 2.5 to 4.5 in the prior art?
A. No.
Q. Okay. So was the stability of a product with a known range of 2.5 to 4.5 considered to be a problem in the prior art?
A. No.
Q. And would a POSA have known anything more about the pH of these various products beyond what you've illustrated here?
A. No, they would have no other information.
Q. Now, before Par's patents, was there anything published in the prior art that would have directed a POSA toward the claimed 3.7 to 3.9 range?
A. No.
Q. All right. So now I'm going to jump ahead in your presentation to talk about your obviousness analysis. We'll get back on track.

So let's talk about original Vasostrict, which defendants rely on. Sorry for the delay.

When was original Vasostrict first sold.

A. Let's go to the next slide. So it first --

Q. Sorry. I think I'm pointing at one direction. Go ahead.

A. So the first sale was in November of 2014.

Q. All right. And now there has been some discussion of the label of original Vasostrict at various times. Could you just explain that a bit?

A. Yes. There was an April 2014 label that has been discussed and --

Q. That's DTX-36?

A. Yes, DTX-36. There was a September 2014 label, DTX-45, and that was the label that the product was first sold under, and then there was a May 2015 label, DTX-132.

Q. Okay. And what is the label --

THE COURT: Just so the record is not going to mess up, the slide says DTX-46 for the September 2014 label?

THE WITNESS: I'm sorry.

THE COURT: I don't know which is right, but I don't want to deal with it post-trial.

MR. LOEB: Let me just --

THE WITNESS: That's my mistake because I was reading up there and it looked like a five.

THE COURT: So the slide is right?

MR. LOEB: Your Honor, it's 46.

THE COURT: All right. Thank you.

BY MR. LOEB:

Q. What do those labels say about the pH of original Vasostrict?

A. It indicates that the pH would adjust with acetic acid at 3.4 to 3.6.

Q. Okay. Did the original Vasostrict label say anything about impurities within the original Vasostrict products?

A. No, it doesn't.

Q. Okay. Now, defendants' experts talked about the original Vasostrict registration batches, particularly number 310571. Was 310571 ever on sale or in public use?

A. No. Let's look at the next slide. So this lot was manufactured early in 2012. It had a two-year dating and so it expired in early 2014 and then the sales began for original Vasostrict in 2014, so it was not on sale.

Q. How many different registration batches of original Vasostrict were there?

A. There were three.

Q. All right. And Dr. Park talked about the one. Did you investigate the pH behavior of all three original Vasostrict batches?

A. I did.

Q. **What did you find?**

A. **Well, these are the pH data for all three batches, which were all between 3.5 and 3.6 with the exception of the 18-month reported value for 310571, in which the pH was measured at 3.8. Then 24 months of pH was measured again and was at 3.5.**

Q. **Was that pH 3.8 value ever investigated or shown to be a valid number?**

A. **No, no. There was no out of specification investigation for that value because it was still within the specification for this product. So we don't know if there was an analytical error or a lab error associated with that measurement.**

Q. **So I have to take a digression with you a little bit.**

Before we can really talk about whether original Vasostrict had the elements of the claims, there's a claim limitation which hasn't really been discussed in the case so much as all yet an that's the impurities limitation. I was hoping that you could explain what that is?

THE COURT: Can you just stop for one second?

MR. LOEB: Yes, Your Honor.

THE COURT: Can I have the lawyers come to sidebar?

(Sidebar conference held as follows.)

THE COURT: All right. I'm sure there's an answer to this and maybe my brain is just foggy. It's Friday, three days of trial.

In light of the withdrawal of the anticipation defense, why does this matter, what you are going into?

MR. LOEB: So anticipation is the epitome of obviousness.

THE COURT: Okay.

MR. LOEB: So the relationship between the prior art and the claims is critical. They need to show that somehow you'll get from the prior art to the claimed invention, but what I'm doing is doing the part of the analysis. It's the third step, and that is the Graham analysis, which is the difference between the prior art and the asserted claims.

MR. BLACK: They're still claiming original Vasostrict is relevant to obviousness.

THE COURT: I figured as much. No, no. I got that much. But what you are going into, is it about -- go ahead.

MR. LOEB: I was just going to say that the scientific question that we were discussing earlier on Mr. Black's motion is still relevant to the case, whether the original Vasostrict products are the same or different than the claims. Just because you ruled that the claims are not

anticipated, that doesn't make that issue moot.

THE COURT: Why is it relevant -- I know you say it's prior art. It's considering the obviousness analysis.

MR. HALES: Yes. I think the characteristics of the original Vasostrict as a whole now get into the obviousness analysis. An easier framework within which to look at what are the characteristics of original Vasostrict, the product.

THE COURT: Right.

MR. HALES: All right. And that's one point. The second point is it also does go to the issue of criticality, right, because if you've got -- our criticality argument again is how close are these claims together and they're already really close, we say, within an abutting range, but then when you apply the drift theory to that, they get really, really close.

When you have evidence of products that are part of the prior art that are already drifting, this theory on criticality is further undermined.

THE COURT: All right.

(End of sidebar conference.)

MR. LOEB: May I proceed?

THE COURT: Yes.

BY MR. LOEB:

Q. I was going to ask you about the impurity limitations in the independent claim. Can you explain what that means?

A. Yes. The impurity limitations in claim 1 refer to a range of impurities in an amount of 0.9 to 1.7 percent wherein the impurities have from about 85 percent to a hundred percent sequence homology with vasopressin with SEQ ID Number 1.

Q. Okay. And what's meant by 85 to a hundred percent sequence homology?

A. Let's take a look at an example and it will be easy to see in this example.

So this shows Table 3 from the patent, and what we're doing is we're comparing the sequence of SEQ ID number one, which is vasopressin, with the sequence of one of the degradants. This is the glu4 vasopressin.

So we talked about the sequence before, and in the top, in the blowup there on the right-hand side we list -- I've listed the vasopressin sequence on the top and the sequence associated with the degradant -- the degradant on the bottom.

And what one does is to compare each of the amino acid residues in the sequence and where there is a difference, then, for example, in the fourth position for vasopressin labeled Q, which is glutamine, that's the amino acid, and in the degradant, that is converted to glutamic

acid, which has a symbol of E. And that's the only change that occurs in the degradation of vasopressin to glu4 vasopressin. So eight of the nine amino acids are matches and so the percent sequence homology therefore is 88.89 percent.

Q. So would that be within or without the impurity -- or the SEQ percent sequence homology portion of the impurity limitation?

A. That's correct. This would be within the -- the 85 to 100 percent sequence homology.

Q. Okay. So what do you need to do to know whether a product has .9 percent to 1.7 percent wherein the impurities have from about 85 to a hundred percent, sequence homology?

A. Well, you have to identify what the degradant is there and compare its sequence to SEQ ID Number 1.

Q. You have to add them all up after that to ask that question?

A. Yes. Yes. I mean, you have to add up the ones, the matching ones and divide by the total number of amino acids to get the percent.

Q. Okay. And in looking at defendants' prior art where they have provided impurity levels, do you know the identity of every impurity in each of those prior art samples?

A. No. So there are some of the degradants which have been identified and identified as falling within the 85 to

100 percent, but there are also unknown degradants, which may or may not have the required sequence to be included in this calculation of 0.9 to 1.7 percent.

If we go to the next slide, for example, the claimed range is 0.9 to 1.7 percent. We have identified impurities and then total impurities.

So, for example, if the identified impurities are outside the claimed range and the total impurities are outside the claimed range, then we know that the requirements of this element of claim 1 have not been met.

If total impurities is outside the claimed range but the identified ones are within the claimed range, then we're not sure whether or not the -- the claims are met. And if both, the total impurities and the identified homologous impurities are within the claimed range, then clearly that would meet the limits of the claim.

Q. All right. Did you evaluate the level of impurities with the claimed sequence homology within original Vasostrict batch 310571, particularly at the time that it was measured at the pH of 3.8?

A. Yes. Let's go to the next slide.

Q. What did you find?

A. So this is the impurity information that was obtained at 18 months when the pH value was at 3.8, and what I'm showing is the individual identified impurities, and then at

the bottom of this table -- on the right-hand side of the bottom of this table, there is the impurities of both the ones that had been identified in Table 3 as homologous impurities, which were some of the ones that are listed above, and that's 2.6 percent, and then the impurities having, or the impurities, the total impurities for that sample was 2.9 percent.

So both the homologous impurity total and the total impurities fell outside of the claimed range. So that element of claim number one was not met at pH when the sample -- when the sample was -- at the 18-month sample.

Q. All right. Have you prepared a slide to summarize what data you have seen for batch 310571 at the time that it had that 3.8 pH?

A. Yes. Let's go to the next slide.

So this indicates on this slide -- well, first of all, this is a registration batch that was never sold and not in public use. At 18 months it did have a pH within the claimed range, but it did not satisfy the purity limitations concurrently, both in terms of total impurities and in terms of most of the specific impurities, which are listed in the dependent claims.

Q. All right. Now, another batch that I believe Dr. Park testified about a little bit was lot 788436, which he said was a commercial lot. Have you prepared a slide that

analyzed what we know about that product when it was on sale?

A. Yes. Let's go to the next slide. So the date of manufacture of this was February 24th of 2015. The first sale occurred and that is when the pH was measured I think at 3.7, as I recall, and then the first sale wasn't until November 11th of 2015, so a number of months after the date of manufacture. And so there was no data that was available at that time for this batch, there was no pH data and no impurity data.

Q. All right. And where did you find this information?

A. So the date of manufacture was in DTX-1378.

Q. And what was that document?

A. That was the certificate of analysis for that batch.

Q. All right?

A. And date of first sale was in DTX-1362, which contains sales data for original Vasostrict.

Q. All right. Did Dr. Park present any measurements of the pH or impurities within lot 788436 at the time that it was on sale?

A. No.

Q. All right. So you mentioned DTX-1378. Do you recall how many commercial lots of original Vasostrict are identified within that certificate of analysis document, 1378?

A. My recollection is 15.

Q. Okay. And does that document -- you already answered that question. All right. So of the 15 lots, how many did Dr. Park identify as being measured with a pH of 3.7, 3.8 or 3.9 at the time that those products were on sale?

A. There were none.

Q. All right. And how many had a pH that was 3.7 or higher at the time of manufacture?

A. One.

Q. All right. Have you prepared a slide to summarize what your observations are about other commercial original Vasostrict lots?

A. Yes. Let's look at the next slide, which has the stability data for the commercial original Vasostrict lots and it's a little hard to see on this, but all of the pH values were 3.6 or lower.

Q. And those are lots 788442, 788432, 788433, 788435, and 802171?

A. That's correct.

Q. And that information is found in DTX-360?

A. That's correct.

Q. All right. I'd like to ask you about Pitressin now, another prior art product that Dr. Park talked about. What was publicly known about the pH of Pitressin?

A. So, and the next slide, the label I think was

published as part of the FDA biopharmaceutics review, PTX-146, and the pH that was published was 3.6.

Q. Was there any information publicly available about either the impurities in Pitressin or the rate of impurity formation in Pitressin?

A. No, there was no information.

Q. All right. Now, Dr. Park mentioned lot 78495 of Pitressin. Have you looked at the stability data for that lot?

A. Yes.

Q. And what did you find?

A. Well, let's go to the next slide. So there was a piece of data at three-month stability which showed a pH value was in the range, but once again, the impurity levels were outside of the claimed range as carved out in claim number one and most of the impurity levels for the dependent claims were also outside of the claimed range.

Q. Would a POSA have known the specific pH values of any Pitressin product at the time that it was on sale or in public use?

A. No, they would not.

Q. All right. And what do you conclude about whether Pitressin lot 784 -- I will phrase it a little differently. Are there any differences between lot 78495 and the asserted claims?

A. **Yes. This lot did not meet the impurity and pH limitations concurrently.**

Q. **All right. Now, I would like to talk about your obviousness opinion. Have you reviewed each of the articles of prior art or the documents that Dr. Park and -- I'm not sure if Dr. Chyall mentioned any, but that defendants' experts have asserted as rendering the claims obvious?**

A. **Yes, I have.**

Q. **And in your opinion, does the prior art, either original Vasostrict or the April 2014 Vasostrict label, render the asserted claims obvious?**

A. **No, they do not.**

Q. **All right. Could you tell me the approach that you were instructed to take in order to make that conclusion?**

A. **Sure. Let's go to the next slide. So I was instructed to look at the scope and content of prior art, the level of ordinary skill in the art, to look at differences between the prior art and the claims at issue and objective evidence of nonobviousness. Also the reason or motivation to combine the art into the claimed inventions and the reasonable expectation of success in achieving the claimed invention.**

Q. **And in your analysis, did you follow this procedure?**

A. **I did.**

Q. **And have you summarized your conclusions?**

A. **Yes. Let's go to the next slide.**

So I found that there was no motivation to combine or modify the prior art. Preparations of vasopressin were believed to be stable, safe and effective. There was teaching away, as we saw. For example, the Bi article, but also the FDA statements, which clearly state that the pH of maximum stability was 3.4 to 3.6 and outside that range, the product was less stable.

There was data, there was no data -- well, I mean, there was criticality data that we looked at and no evidence of inherency. In addition to that, there was not a reasonable expectation of success. I think even the inventors were surprised that the claimed pH range was -- provided better stability than the prior art pH ranges.

Q. **Okay. So we've already talked about the scope and the content of the prior art and I asked you questions about your definition of a POSA in your previous testimony.**

Did you apply that same definition here for this analysis.

A. **Yes.**

Q. **All right. And I asked you for that analysis whether it mattered whether you used defendants' experts definition or your own. Would that matter for your obviousness analysis?**

A. **No.**

Q. **Okay. So I'd like to talk about the differences a little bit more.**

Did defendants' experts show that the April 2014 Vasostrict label disclosed the pH and impurity limitations? Let's head to your summary.

A. **No. The original Vasostrict --**

Q. **I asked you out of order.**

A. **I'm sorry.**

Q. **That might be what's confusing. I asked you about the label.**

A. **Yes. Okay. The labels didn't contain impurity information and, you know, the pH information was not in the claimed range.**

Q. **And what about the original Vasostrict product?**

A. **So, again, the pH and impurity limitations were not met concurrently.**

Q. **All right. Now, Dr. Park, this is a quotation from Dr. Park's report that summarized the testimony. He argued that the claim range was abutting the range that was known in the prior art and therefore an ordinary skilled artisan would expect those two ranges to exhibit similar properties.**

Do you agree with Dr. Park about that?

A. **No. Let's go to the next slide. So --**

Q. **Other.**

A. **There is no overlap between the pH range 3.4 to 3.6 and 3.7 to 3.9. A person of ordinary skill would have known -- would know that the pH effect, even with small differences in pH, can affect stability and additionally, one would expect, I would expect, a POSA would expect that a product produced in different pH ranges would have different properties. In addition to that, I'm not exactly sure what he meant by similar properties. It wasn't really a term that I could find -- define well or at all.**

Q. **All right.**

A. **In addition to that, of course, there's prior art that comments on the regions of optimal stability, the FDA statements and the Bi article.**

Q. **I would like to move on to the motivation aspect of the obviousness analysis. Would a POSA have been motivated to modify or combine the prior art to achieve the claimed invention?**

A. **No. I see no motivation to modify or combine.**

Q. **All right.**

A. **A person of ordinary skill would not have seen this.**

Q. **Did you hear anything from Dr. Park about a motivation to modify or combine the prior art?**

A. **No, I didn't.**

Q. **How many lots of original Vasostrict and Pitressin were sold before the time of the patent, the priority date**

of the patent?

A. I'm sorry. Repeat your question.

Q. Sure. How many lots of original Vasostrict and Pitressin were sold before the priority date of Par's '785 and '209 patents?

A. Well, there were hundreds of lots that were sold.

Q. Did Dr. Park provide an opinion about all of the lots of original Vasostrict and Pitressin that were sold?

A. No. He picked out a couple of them.

Q. Now, if you look at the prior art teachings as a whole, was there anything that would have directed a POSA to the specific lots of original Vasostrict or Pitressin which defendants' experts identified?

A. No. There was nothing that would direct them to any particular lot.

Q. And would a POSA have known the specific pH of a lot that defendants' experts identified?

A. No, they would not.

Q. And would they have known the specific impurities of a lot that defendants' experts identified?

A. They would have no impurity, no.

Q. Now, Dr. Park made brief reference to a Lithuanian patent. Do you recall it? DTX-144?

A. I do.

Q. All right. When was that patent published?

A. **Let's go to the next slide. So this is a patent that was published some 18 years before the priority date. It was published in April 1999.**

Q. **Okay. And how long was it -- I think you actually said. Have you seen any evidence that anyone used the information in the Lithuanian patent for any purpose?**

A. **No, I have not seen any evidence.**

Q. **All right. Now, does the Lithuanian patent discuss the type of vasopressin to be used?**

A. **Yes. It says the essence of the invention is that the following components are included in a preparation produced from an active ingredient derived from animal posterior lobe pituitary extract. So this is something which is extracted and purified from an animal's organs.**

Q. **Now, the Court construed the claim term vasopressin as arginine vasopressin as described in SEQ ID Number 1.**

Could you show us how SEQ ID Number 1 is described in the patent.

A. **Yes. Let's go to the next slide. So SEQ ID Number 1 describes -- well, this is an excerpt from the '209 patent, but it's described as a synthetic peptide. So it says that it would be synthetically made.**

Q. **Does the Lithuanian patent teach the use of synthetic peptides?**

A. **No. The Lithuanian patent is dealing with the peptide**

extracted from animal sources.

Q. Okay. Now, in the claim construction hearing, the Court commented, the vasopressin in SEQ ID Number 1 is synthetic vasopressin. Is that how you understood the asserted patents as well?

A. Yes.

Q. Would a POSA expect the optimal formulation for an animal derived vasopressin to be the same as the optimal formulation for a synthetic vasopressin?

A. Not necessarily.

Q. And why not?

A. Well, because there are -- you know, a person of ordinary skill typically develops the products based on the specific API that they -- that they're going to use. And there are differences between APIs that are extracted from animal sources and those which are synthetically produced.

Q. If a POSA were trying to make an improved synthetic vasopressin solution with better stability, would that POSA have sought guidance from the Lithuanian patent?

A. No.

Q. Is there any data or discussion in the Lithuanian patent that indicates that the disclosed range in that patent, which is 3.8 to 3.95, is optimal for the stability of vasopressin?

A. No, there is no stability data in that, in that patent

to rely on. There's no -- there's no stability data.
Q. Would the disclosure of the Lithuanian patent have provided a POSA with a reasonable expectation of success in preparing the claimed synthetic vasopressin formulation?
A. No. Again, there's -- there's nothing there that would give them any indication that the preparation that they, that they discussed is stable at all.
Q. Could you please pull up DDX-2, slide 77 from Dr. Park's presentation. Hopefully, I have the right one. Yes. All right.
So Dr. Park mentioned two public pieces of information, that USP 2009 monograph, which is DTX-136 -- 135.
A. 135.
Q. 135, yes. And DTX-144 is the Lithuanian patent that we've just been talking about. Do either of those two references provide any data about the optimal pH for vasopressin formulations?
A. There is not stability data either in the USP monograph or in the Lithuanian patent.
Q. Do you have an opinion as to whether anything about the USP 2009 or Lithuanian patent would have directed a POSA to the pH of 3.7 to 3.9 for an improved vasopressin formulation?
A. No.

Q. **Can you summarize your reasons why a POSA would not have been motivated to make the -- modify the prior art or combine it in such a way to reach the claimed invention?**

A. **Yes. Let's go to the next slide.**

MR. LOEB: If you could take that down, put our slides back, and I think we're on 51.

THE WITNESS: Next slide. So in all of the asserted art, there was no motivation to improve stability. There was no -- there was not information about impurities and certainly not a motivation to lower impurities to any specific claim level.

There wasn't any motivation or any indication that would lead a POSA to the particular selected lots that were, that were pointed to. In addition to that, of course, there was prior art, which taught away from the claimed range.

In terms of the Lithuanian patent, it's directed toward a different API and it actually has comments that teach away from using synthetic vasopressin. It makes comments about the relative bio activity of the Lithuanian patent, their preparation and synthetic vasopressin.

Q. **All right. I'd like to change topics to the next aspect of the obviousness analysis, which is reasonable expectation of success.**

Did you hear any testimony from defendants'

experts on whether there would have been a reasonable expectation of success in practicing the claimed invention.

A. No, I didn't hear anything from defendants' experts.

Q. All right. I'm going to skip this slide because we talked about it before, but in view of the prior art, would a POSA have reasonably expected to achieve the specific impurity levels which are recited in the asserted claims?

A. No.

Q. And have you prepared a slide about that?

A. Yes.

THE COURT: So before you go there, Mr. Hales, did you put on any evidence of likelihood of reasonable success?

MR. HALES: The evidence we have on that, Your Honor is that there was already actually success with the prior art that was out there.

THE COURT: You don't dispute that the expert, an expert could opine on it?

MR. HALES: Dr. Park did not talk about it. The evidence that is there satisfies it.

THE COURT: Okay.

MR. LOEB: Excuse me. I've forgotten my question.

THE COURT: Your question was -- well, I will let you do that.

BY MR. LOEB:

Q. I think I asked you, would a POSA have reasonably expected to achieve the specific impurity levels which are recited in the asserted claims?

A. No, they wouldn't. Again, the impurities were not known. They weren't there in the prior art and certainly the levels of those unknown impurities were also not, not known.

Q. Have you prepared a slide that summarizes your opinions with respect to the aspect of expectation of success?

A. Yes. Let's go to the next slide.

So there wasn't a reasonable expectation to -- that would --

Q. I'm sorry. Whoa. Go ahead.

A. Oh, I'm sorry. So no reasonable expectation that the claimed pH values would have an improvement in stability and certainly no expectation to achieving any claimed levels of impurities. Again, the impurities were not, were not known.

And, in addition to that, for the Lithuanian patent, there's not a reasonable expectation that synthetic vasopressin could be used interchangeably with the animal derived vasopressin that they described in their patent.

Q. All right. I'd like to leave obviousness now and I'd like to ask you some questions that are relevant to

defendants' inequitable conduct claim.

First of all, have you reviewed the patent applications that led to the asserted patents?

A. Yes.

Q. And have you prepared a slide that illustrates the sequence of patent applications that led to the asserted '785 and '209 patents?

A. Yes. Let's look at our next slide.

So this describes the flow of patent applications which led to the asserted claims as presented in '785 and '209. There were a number of prior patent applications, but importantly, between the '239 patent and the next one in the family, the '526 patent, there was extensive additions to the patent specification, including 60 new columns and eight figures. There were seven examples that were added, including example 14.

So, you know, these were the declaration data, the criticality data that was added then. And then from the '526 patent to the asserted patent, there was an additional example 15 which was added that describes 15-month stability data for the -- the reformulated Vasostrict, which actually practices the patent claims. So that was added to the '785 and '209 patents.

Q. All right. So just so the record is clear, what Dr. Kirsch called the '239 patent, the 9,744,239, which is

DTX-605, and the '526 patent is 9,687,526. That's JTX-1. And then, of course, the '209 patent, JTX-2 and the '785 patent is JTX-3.

So bottom line: Was the information that the Examiner considered when deciding whether to grant the '785 and '209 patents different in any material way from the information that the Examiner had when deciding whether to grant the '239 patent.

A. Well, yes. There was extensively more data, more information that was added. Again, for the '526 patent and then additional information that was compiled for the '785 and '209 patents.

Q. During the prosecution of the '785 and '209 patent, did Par say anything about what portions of the specifications that particularly supported the claims in those patent applications? In other words, the claims that are asserted in this case?

A. Could you repeat your question?

Q. It was a long question. I'm sorry. I'm probably getting a little tired.

During the prosecution of the '785 and '209 patents, did Par say anything about the portion of the patent specification, written description of the patent that particularly support the patentability of the asserted claims.

A. **Well, again, they included all of the criticality data that we've discussed and they included their -- the data that -- the long term stability data that supported the -- the elements of the claims.**

Q. **Okay. So if we go to the next slide, in the June 28th, 2017 office action responses which are from both the '785 and '209 patent prosecution, and PTX-844 and PTX-843 respectively.**

What did the patentee say about relationships between the claims and the patent specification?

A. **Well, so this is an excerpt from those office action responses, and in the highlighted area it says, the present claims are narrowly drawn around the result of example 14 and 15 in the specification. It goes on to say, the tables indicate pH fluctuation between 3.7 and 3.9 over the study period.**

So they provided the data, which were the data for the registration batches and that included impurity data as well as pH data.

Q. **All right. So just to rehash that for a second, were Examples 14 and 15 in the specifications which are now issued as the '785 and '209 patents part of the '239 specification?**

A. **No, they weren't.**

Q. **And what's the significance of the fact that applicant**

pointed out that the tables indicate that the pH fluctuated between 3.7 and 3.9?

A. They're pointing to the fact that the pH values were within the claimed range, 3.7 to 3.9.

Q. All right. And I think you mentioned earlier that -- something about the -- what the samples in Example 15 of the patent are relative to Par's product.

Could you explain that?

A. Yes. These are the registration batches for the reformulated Vasostrict.

Q. Okay. Were you provided by counsel an instruction as to -- how to assess but-for materiality?

A. Yes. Let's go to the next slide. I was told that information is material if but for the individual's intentional misrepresentation or failure to disclose, the Patent Office would not have allowed one or more of the claims of the patent at issue.

Q. All right. Now, defendants argue that failure to disclose information about the April 2014 Vasostrict label was material to the patentability of the asserted patents.

Do you agree with that?

A. No, I don't.

Q. And why not?

A. Well, let's go to the next slide then.

Q. I don't think there is a next slide about this. No. That's on to a different subject.

Do you -- did you assess whether the April 2014 label would invalidate any of the asserted claims?

A. Yes. And it doesn't invalidate the claims.

Q. All right. Same -- well, defendants have contended that the pH range of 3.4 to 3.6 for original Vasostrict is closer than the 2.5 to 4.5 pH range disclosed in the PPC reference and other references before the Patent Office during prosecution.

Do you agree with that?

A. No, I don't. They abut. Either the 3.4 to 3.6 is abutting. The 2.5 to 4.5 is a much broader range.

Q. And did that cover the 3.7 to 3.9 range?

A. Well, it does. It includes the 3.7 to 3.9 range.

Q. Now, Dr. Chyall argued that additional information was allegedly withheld by Par and was material to the asserted claims. So, for example, was the normalized impurity data but for material the asserted claim?

A. No. I think we've seen that whether one looked at the total impurity at four weeks, 40 degrees, or 1 looked at the so-called normalized impurity data at 40 degrees, the results would have been, the conclusion would have been interpreted in the same way, so that would not have changed the assessment.

Q. All right. Now, could we please have DDX --

MR. HALES: Your Honor, sorry.

THE COURT: Yes?

MR. HALES: Being a bench trial, I didn't expect the answer to come out that way. We don't have any problem with Dr. Kirsch comparing whether the technical or scientific showing of the art of the claims are there, but I think we have commented on what the Examiner would do. We ask that that be stricken or not.

THE COURT: Well, fair enough. I am aware that I have to kind of independently infer what the Examiner would have done.

MR. HALES: I'm just making it for the record. Obviously, agree everybody agrees, the witness should be --

THE COURT: I thought state of mind versus what they would have done, I thought we earlier addressed this. I will let it slide. We'll figure it out.

BY MR. LOEB:

Q. Let me ask a similar question. Does the normalized impurity data render any of the asserted claims invalid?

A. The normalized?

Q. No. Actually, the normalized?

A. The normalized? No, it doesn't.

Q. Now, could I see tab DDX-417.

Yes. So these are Dr. Chyall's slides and, in

particular, do you remember Dr. Chyall testifying about this slide.

A. Yes, I do.

Q. And do you recall that he raised an issue over the fact that three of the data points for 3.5 pH, 3.7 and 3.8 were negative numbers and weren't shown on the graph?

Do you recall that?

A. I do recall that.

Q. All right. Now, first of all, did you hear Mr. Vandse's testimony regarding this issue today?

A. Yes, I did hear that.

Q. All right. And given Mr. Vandse's testimony and your own independent evaluation of this, these three negative data points, what do you understand the reason for the negative data points to be?

A. Again, the changes that occurred one month at 25 degrees were very small and so basically, some of the values just reflect noise in the data and as a consequence there were some negative numbers that were generated which would not fall on this particular chart, which has lower value of zero, so, you know, it was just noise.

Q. Are these three data points in any way important to the question of whether the pH range is critical or not?

A. No.

Q. And why not?

A. **Well, because the 25-degree data in this region is not especially informative. I think one needs to go look at the data at 40 degrees where there's a significant change to see the pH effect.**

Q. **In your opinion, was the 25-degree graph, which appears in the prosecution in many cases -- that's the one that Dr. Chyall pointed to -- it's DDX-10 at 2365, misleading in any way?**

A. **No. It simply represented the -- the data. It wasn't misleading. The raw data was certainly available.**

Q. **When you say the raw data was available, did the Patent Examiner have this data at the same time that she was considering these figures?**

A. **Yes.**

Q. **All right. Now, another thing that Dr. Chyall mentioned was the pH specification in the reformulated Vasostrict NDA.**

Do you consider that pH specification to be material to whether the claims are patentable.

A. **No, I don't think the specifications are relevant to, you know, the issues of criticality and, you know, again, we've talked about this. There's not the same thing to find the region of maximum stability that is not the same as -- that's not reflective in the specification.**

Q. **Now, defendants have asserted that the November 2015**

declaration by Dr. Kannan, which was discussed quite a bit this morning, defendants asserted that that declaration was false. Was the November 2015 declaration from Kannan filed during the prosecution of the patents-in-suit?

A. No.

Q. Have you prepared a demonstrative about that?

A. Yes. Let's look at the next slide.

MR. LOEB: Could we go back to the slides, please.

BY MR. LOEB:

Q. Okay. So in which application was the November 2015 Kannan declaration provided to the Patent Office?

A. It was provided for the '239 or in the '239 patent application.

Q. All right. Now, you'll recall that November 2015 Kannan declaration addressed the April 2014 Vasostrict label.

Do you remember that?

A. Yes.

Q. All right. And based on your analysis that you've already provided, would the April 2014 Vasostrict label have invalidated the asserted claims of the '785 and '209 patents?

A. No.

Q. Now, did you look at the claims for the '239 patent?

A. **I did. Let's go to the next slide.**

Q. **All right. Now, one of the claim limitations in the '239 patent claims, claim 1, Section A four reads, zero to two percent vasopressin degradation product.**

Does the April 2014 Vasostrict label teach anything about vasopressin degradation products or their levels?

A. **No, it doesn't.**

Q. **And do you recall Dr. Park seemed to be arguing that the April 2014 label inherently disclosed zero to two degradation products.**

Do you remember that?

A. **Yes.**

Q. **And how many batches of vasopressin did Dr. Park look at in order to reach that conclusion?**

A. **I don't recall that there were any.**

Q. **All right. Now, had Dr. Park shown that limitation is present? Just to be clear, the zero to two percent degradation products limitation was present?**

A. **No, he hasn't.**

Q. **Now, so in your opinion, would the April 2014 Vasostrict label have invalidated claim 1 of the '239 patent?**

A. **No.**

Q. **All right. So before I go, Dr. Kirsch, you've heard**

the testimony of Drs. Park and Chyall and all the arguments that they made. In all of that testimony, did you hear anything that causes you to doubt your conclusion that the '209 and '785 asserted patents are valid and enforceable?

A. No, I have not heard anything. They are in my opinion valid and enforceable.

Q. And did you do your best to address every single one of the arguments that they made?

A. I did.

MR. LOEB: Thank you very much. Exhibits, I think.

Your Honor, Par moves to admit JTX-1, JTX-2, JTX-3, PTX-146, PTX-309, PTX-411, PTX-843, PTX-844, DTX-46, DTX-53, DTX-125, DTX-128, DTX-132, DTX-173, DTX-1143 and, lastly, DTX-1378.

MR. HALES: No objection, Your Honor.

THE COURT: All right. They're admitted. Thank you.

(JTX-1, JTX-2, JTX-3, PTX-146, PTX-309, PTX-411, PTX-843, PTX-844, DTX-46, DTX-53, DTX-125, DTX-128, DTX-132, DTX-173, DTX-1143 and DTX-1378 were admitted into evidence.)

THE COURT: All right. Mr. Hales, how long are you going to be?

MR. HALES: My guess is 45 minutes.

THE COURT: Okay.

MR. HALES: 45, I think.

THE COURT: All right. Then we'll take a quick break.

(Short recess taken.)

- - -

(Proceedings resumed after the short recess.)

THE COURT: All right. Please be seated.

All right. By our count, you all are both at nine hours and 50 minutes. There have been a lot of goings on and whatnot, so I'm going to give you -- you know, you should aim for 30 minutes and we'll see if there's redirect.

I'm still going to be a little generous here. I have a few questions. Let's try to move fast. All right? Yes?

MS. WU: I have a few questions separate than Mr. Hales.

THE COURT: That's fine.

MS. WU: Thank you, Your Honor.

MR. LASKY: Your Honor, may I approach?

THE COURT: Yes.

MR. HALES: May I proceed, Your Honor?

THE COURT: Please.

CROSS-EXAMINATION

BY MR. HALES:

Q. **Good afternoon, Dr. Kirsch.**

A. **Good afternoon.**

Q. **Nice to speak to you again. Just one quick question. The FDA has not approved any increase in shelf life for Par's Vasostrict product?**

A. **That's my understanding.**

Q. **Now, you talked about in the context of criticality, you were looking at 25 C graphs and 40 C graphs. Right?**

A. **That's right.**

Q. **I think the point was at 40 C, you're going to increase the rate of degradation?**

A. **Yes.**

Q. **At least that was one of the reasons that you preferred or thought it was more appropriate to rely on the 40 C graph?**

A. **That's correct.**

Q. **And I think the general principle you're relying on is at a higher temperature, things will degrade faster?**

A. **Yes, in general, but you can just look at the data and see that that is true.**

Q. **And a POSA would expect that conversely that at lower temperature, things would tend to degrade more slowly?**

A. **Yes.**

Q. **A so POSA would know that if you put something in a refrigerator, for example, you would expect to slow the rate**

of degradation?

A. That's correct.

MR. HALES: Now, could we have Dr. Kirsch's slide 47.

BY MR. HALES:

Q. This is a slide in your direct examination, Dr. Kirsch. I want to focus on the right.

So you say here -- thank you. Okay. Product with 3.4 to 3.6 and one with pH 3.7 to 3.9 in your opinion are expected to have different properties. That was your point?

A. Yes, that's correct.

Q. Now, the 3.6 there is 3.64. That goes up to 3.64, of course, right?

A. Yes.

Q. And 3.7 goes down to 3.65?

A. Correct.

Q. So if we factor that in, what you've suggested here is that a product with 3.64 and one with pH 3.65, you're opining that those are expected to have different properties?

A. Yes.

Q. All right. Now, I take it that's a hundredth of a pH difference; is that right?

A. That's correct.

Q. **And so I take it that you would agree that it would be hard to discern the difference in stability between a formulation with a pH of 3.64 versus 1 of 3.65?**

A. **Yes. I would add to that that it would even be hard to do the experiment to observe the difference with that degree of separation.**

Q. **Right. And that's because the separation is so slight? Correct?**

A. **Well, it's also because there are limitations in terms of pH control devices.**

Q. **All right. And so then I take it it would also be very difficult to construct an experiment to discern the difference in a formulation that was prepared at 3.65 and compare that to one that was prepared at 3.64 initially, then for, say, five minutes, drifted up to 3.65?**

A. **Yes. That would be a difficult experiment to do as well.**

Q. **And I think you would agree that a POSA would not expect there to be any meaningful difference at all in an experiment where one sample with 3.65 five for a period of time and another with 3.64, but drifted to 3.65 for say five minutes?**

A. **Yes. Well, of course, it would depend upon the conditions in which you did the experiment, but --**

Q. **But you would agree --**

A. **In general, it would be a difficult experiment to run, yes.**

Q. **And yet they would not expect there to be any meaningful difference in the stability outcome between the two samples?**

A. **Yes. I mean, it would be -- if you did it at a high enough temperature, you might be able to discern a difference, but it would be -- it would be difficult.**

Q. **Certainly not at room temperature or 40 C temperatures that you've talked about?**

A. **I have not seen that kind of rate that would allow for a difference to be observed.**

Q. **You have not seen that kind of rate? I want to make sure I heard you?**

A. **Yes, I have not seen that, you know, the rate at 40 degrees, you know, required a series of time much greater than five minutes.**

Q. **Just to make sure I'm hearing you, because maybe I'm having a little bit of trouble with picking up, but I think a POSA would not have any expectation that there would be a difference in stability in the -- in a comparison of a sample that was 3.65 at room temperature for a period of time as compared to one that was 3.64 at room temperature for a period of time plus spending five minutes at the 3.65 number.**

A. **Well, again, it would depend upon the conditions in which you did the experiment. So I mean if you did it at a high enough temperature such that those experiments could have an effect, then you would see a difference.**

Q. **Right. I think in there, it was a long hypothetical, but I used 25 C. A POSA would have no expectation of any difference whatsoever in what I described 25 C. Fair?**

A. **It would be difficult to see any difference, that's correct.**

Q. **Just to be precise about it, you wouldn't expect there to be a difference in that comparison; is that correct?**

A. **So the hypothetical, again, is --**

Q. **Let me put it this way. I think what you are saying is that if there was a difference at all, it could be so small that you wouldn't be able to detect it. Is that fair?**

A. **Yes.**

Q. **All right. Now, you also talked a little bit about statistics, or a fair amount about statistics. So I think you were talking about statistical significance, and if I followed -- statistical significance is a way of thinking about whether a measurement you've made is reflective of the true value of what the measure is. Is that fair?**

A. **Say that again.**

Q. **Let me try it a different way.**

A. **Yes.**

Q. **If you looked at the differences between certain values and you consider whether they were statistically significant differences; is that right?**

A. **Right.**

Q. **That's in essence a way of asking, I've measured a difference between two things: Is it a real difference or is it one that maybe is attributable to random error in the measurement process?**

A. **Yes, I would agree with that.**

Q. **Okay. Now, are you equating statistical significance with criticality?**

A. **I'm using statistical difference to make, to determine whether or not there is a difference. So, you know, if the difference is statistically significant, then it could well be critical.**

Q. **And I guess the question is: Is it your opinion that if you see a difference in stability between two samples that is statistically significant, that that means it is a critical difference or a critical difference between the stability?**

A. **Well, I think the criticality question goes to the pH conditions and you are using the stability data to determine whether or not there's a critical pH.**

Q. **Right. And the question is: You say the claimed range of 3.7 to 3.9 is the critical pH range; right?**

A. **That's right.**

Q. **Right. And so if you have an observation where the stability of something in that range is statistically different than the stability of something outside that range, is that in your opinion sufficient to satisfy the criticality question?**

A. **I think in this instance, that is true, yes.**

Q. **Now, you would agree, I think, that there can be statistically significant differences, in other words, they reflect in your analysis something other than error, but the difference could still be very small in terms of real-world impact; is that correct?**

A. **In terms of real world impact?**

Q. **Correct.**

A. **Well, again, the criticality valuation has to do with how the pH affects the rate of either appearance of impurities or the disappearance of drug. So it's really a question of whether or not there is a pH which is critical to the rate, so you're looking for the minimum in the pH profile which corresponds to a minimum in the rate of degradation.**

Q. **All right. Let's put up Dr. Kirsch's slide 6-23.**

All right. This is a slide that was used in your direct examination; is that right.

A. **That's correct.**

Q. **And this reports to a statistical analysis that you did with respect to criticality?**

A. **That's correct.**

Q. **All right. And you compared -- you looked at where you saw statistically significant differences in materiality from inside the claimed range of 3.7 to 3.9, as compared to a pH value outside that range; right?**

A. **That's what I did. Exactly.**

Q. **Okay. So if we look at 3.7, all right, 3.7 to 3.9 is a statistically significant difference; is that correct?**

A. **Yes.**

Q. **All right. So within the claimed range, one of the values actually looks more like the data outside the claimed range; is that correct?**

A. **I don't -- I'm sorry. The 3.9 data doesn't look like something outside the range.**

Q. **Let me take it a different way?**

A. **Okay.**

Q. **I will move on in the interests of time with 3.6. Let's just look at 4.0?**

A. **Yes.**

Q. **4.0. In your analysis, you couldn't identify any statistically significant difference between the stability of pH 4.0 and the stability at either 3.7, 3.8 or 3.9; is that correct?**

A. **In the analysis of the rate of impurity appearance, that's correct.**

Q. **Correct.**

A. **But --**

Q. **Yes?**

A. **But remember that --**

Q. **Mr. Black will be able to ask you more questions. I'm just trying to make sure I understand --**

A. **All right.**

MR. LOEB: Or Mr. Loeb.

MR. HALES: Sorry.

BY MR. HALES:

Q. **So if you look at this criticality chart that you put up, and this is -- well, strike that. Essentially, you have -- the difference between 4.0 and 3.9 is not statistically significance; is that correct?**

A. **That's -- that's correct. But, again, this is only part of the story.**

Q. **Okay. If you -- -- moving on in the interests of keeping it -- okay. So let's pull up Dr. Kirsch's slide 38.**

All right. Now, in your testimony, you talked about these lots listed on slide 38, 788442, 788432, 788433, 788435, 802171, and opined that all of those lots have pH values 3.6 or lower; is that correct.

A. **That's correct.**

Q. **And is that true throughout their livesf, their shelf life as you recall?**

A. **Yes, as I recall.**

Q. **Okay. Now, let's go to DTX-360.25. This is the exhibit from which you got the data about these lots; is that correct?**

A. **Yes.**

Q. **DTX-360?**

A. **I believe so, I believe so.**

Q. **Okay. So DTX-360, if we look in the upper left, this was an annual stability lot for 2015.**

Do you see that.

A. **Yes.**

Q. **All right. So that's an original Vasostrict lot; is that right?**

A. **That's correct.**

Q. **Okay. And then you have stability data for, if we blow up this row up here. If we can blow up the top row quickly, we can see where we have stability data for this lot.**

So we have stability data at three months, initial pH reading, and then three months, 6 months, 9 months, 12 months, 18 months, 24-month stability; is that correct?

A. **Yes.**

Q. **Okay. So can we blow up the columns? Let's blow up the 12-month column.**

All right. And this is at 12 months. Right? So these are the impurities, the specific impurities that are recited in claims; is that correct? You can see here in the -- on the left column, which is blown up, which has the list of impurities, it's a little bit -- they're a little bit small, but you see gly9, the glu4 for, the D-ASN, dimer, ASV5, those are impurities and specific ones in dependent claims; correct?

A. **Yes. I don't think the dimer is in the claim.**

Q. **Thanks for that correction, But otherwise, other than that dimer, the other impurities listed are in the dependent claims?**

A. **Yes. Dependent claims, yes.**

Q. **Okay. And so claim 2 calls for an impurity level of .1 to .3 gly9.**

Do you remember that?

A. **I have not memorized all of those.**

Q. **In the interests of time --**

A. **Yes.**

Q. **-- if we go down the 12-month month column, the reported level of impurities, the 12-month mark, .03 for gly9?**

A. **Yes.**

Q. **And glu4 is .03 level for that impurity?**

A. **Mm-hmm.**

Q. **I am saying that wrong. Late in the day. 0.3?**

A. **0.3.**

Q. **Thank you for that clarification, all right, for gly8?**

A. **Correct.**

Q. **0.3 for glu4?**

A. **Correct.**

Q. **0.1 for the D-ASN?**

A. **Correct.**

Q. **The Asp5 is not reported?**

A. **Yes.**

Q. **That's a way of saying that they didn't find any there?**

A. **I don't know. I mean, usually, they have a not detected, so I'm not sure what not reported indicates.**

Q. **All right. And then we have Acetyl-AVP 0.2?**

A. **Correct.**

Q. **And on the total level of impurities, 1.7. Do you see that? That's correct?**

A. **Well, that's what it says, yes.**

Q. **Okay. Now, this lot if we go back to the upper left and look at the blow up here, it was manufactured February of 2015?**

A. **Correct.**

Q. **Right? And so if we pull back up that first column, 12-month column again. Oh, there it is.**

Okay. So if we add up these specified levels of the impurities, the specific one, you've got 0.3 plus 0.3 plus 0.1 plus 0.2 for a total of 0.9 of those identified specific impurities?

A. **Yes.**

Q. **All right. The claim requires 0.9 to 1.7 of those impurities; is that correct?**

A. **Of the homologous impurities.**

Q. **Right. The ones I added up were homologous impurities?**

A. **They were. I mean, they weren't necessarily all of them, but they were.**

Q. **So this is the evidence we have of what was available; right?**

A. **Well, we have the total.**

Q. **Yes.**

A. **1.7.**

Q. **Right. And so this -- now, okay. All right. Now, just to confirm Your Honor -- sorry. Dr. Kirsch.**

THE COURT: Thank you. I would not be able to answer these questions.

BY MR. HALES:

Q. **The pH, all right, that's reported for this sample is**

3.6 all the way across, okay, stability profile.

A. It may not be on this sheet. There we go. It may be on the next page.

Q. Yes. Next page. Okay. There we go. Thank you.

All right. So we can see if we look across and this mirrors up to the month across the row where the pH is recorded as 3.6, 3.6, 3.6, 3.6, 3.6, 3.6, 3.6, right through the shelf life.

A. Correct.

Q. But you understand that the -- you understand that the -- there have been -- well, let's just look at DTX-258. That would be easier, more efficient.

DTX-258 is a -- DTX-258 is a letter from the Food and Drug Administration regarding a citizen's petition. Are you familiar with this?

A. I don't believe so. I don't recall seeing it.

Q. Let's take a look at page 5. And under the conclusion, what's concluded in here is for the reasons stated above --

MR. LOEB: Your Honor, objection. He already asked whether Dr. Kirsch has any knowledge of this document. Dr. Kirsch testified he didn't.

MR. HALES: I'm going to ask him this question about it and see if this conclusion is consistent with his understanding.

THE COURT: Is the document in evidence?

MR. HALES: This -- I don't think it is. I will just ask the question.

THE COURT: Take the document down and ask him a question. Ask him what his understanding is and then we'll go from there or does he agree with a certain understanding.

BY MR. HALES:

Q. **Do you agree that there has been no indication of any safety concern in relation to original Vasostrict?**

A. **I'm not aware of any.**

MR. HALES: One minute, Your Honor. I just want to make sure I get the last, the most important thing, Your Honor.

Okay. All right. Can we pull up Dr. Kirsch's slide 26.

BY MR. HALES:

Q. **All right. This was another slide you talked about in your criticality discussion, Dr. Kirsch; is that right?**

A. **Yes, that's correct.**

Q. **And just so I understand your opinion that you are doing here, what you are doing is comparing the reformulated Vasostrict data that's on the slide, right, against original Vasostrict data; is that correct?**

A. **That's correct.**

Q. **And the context in which you are doing that is that**

reformulated Vasostrict data here is a representation -- is an embodiment of the claims; right?

A. **Yes, that's correct.**

Q. **And original Vasostrict is not covered by the claims; is that right?**

A. **Yes, that's correct.**

Q. **And so you're trying to compare reformulated, which is covered, against original, which is not covered for purposes of seeing whether there's a critical difference in claimed pH; right?**

A. **I'm not using this to determine if there's a critical difference, I'm using this as support for my evidence that there is a critical difference.**

Q. **Okay. And what you see is the, you've looked at the increase in total impurities, which you've averaged at 4.5 percent for original Vasostrict; is that correct?**

A. **That's correct.**

Q. **And 3.5 percent for reformulated?**

A. **Yes.**

Q. **Now, both of those values, 4.5 percent and 3.5 percent are through the entire shelf life of the product; correct?**

A. **They're 12 months. 25 degrees.**

Q. **That is the shelf life at 25 degrees?**

A. **Yes.**

Q. **Both of those values, 4.5 percent and 3.5 percent for**

the end of shelf life time frame are lower than the amount of impurities that could be in the product at day one; is that correct?

A. **Yes.**

Q. **Now, if you look at slide 27, now you've done a similar comparison where you're comparing reformulated Vasostrict batches which are covered by the claims; is that correct?**

A. **Correct.**

Q. **So Eagle's SVA2 and SVA3, which are not covered by the claims; is that correct?**

A. **Correct.**

Q. **I mean, what you are saying here is that SVA2 and 3 from Eagle's data would not infringe the claim; correct?**

A. **That's correct. They would not infringe the claim.**

Q. **All right. And so you've got now, and the data you have here is 5.5 percent for SVA2 and 3 as compared to 3.5 percent for the reformulated Vasostrict; right?**

A. **Right. I left out SVA1.**

Q. **Right. And this is again at the 12-month shelf life expiration; is that correct?**

A. **Correct.**

Q. **Now, the 12-month shelf life amount of allowed impurities is 17 percent in both cases; is that right?**

A. **That's my recollection.**

Q. **Okay. So in both cases, you're well below the allowable amount of impurities at the room temperature expiration point?**

A. **Well, I don't know if the specifications for Eagle's have been approved, but I think that's what they have submitted for approval, as I understand it.**

Q. **All right. Now, you also talked for a moment about the Bi reference for a few moments. Do you recall that?**

A. **Yes.**

Q. **So in the Bi reference, and we can pull up PDX-6-6.**

This is the Bi reference that you talked about, which is titled effect of buffer pH, buffer concentration, et cetera; is that correct?

A. **Correct.**

Q. **Now, in this study, there are a number of formulations or studies that include different buffers than the ones that exist in original Vasostrict or reformulated Vasostrict; is that correct?**

A. **Specifically in the figure that I showed, phosphate buffer was used for the studies.**

Q. **Now, is it correct that there are no studies -- sorry. Yes, there's no samples or studies in the Bi reference where a sample was formulated or prepared at the pH of 3.4, 3.6, but then allowed to drift or drifted up to 3.7 and then an assessment of its stability compared with other**

formulations?

A. No, there were no studies like that.

Q. Right. In fact, in everything that you've seen, whether in any of the references you've identified for teaching away and any of the patentee's data submitted to the Patent Office anywhere. In fact, you've not seen studies comparing the stability of a formulation that is in 3.7-3.9 compared to the stability of formulation that was formulated 3.4 to 3.6 and then drifted for a time, say five minutes, into 3.7, 3.9?

A. No, I have not seen anyone conduct that study, no.

Q. And the same -- this is my final. And if the same question, if the comparison is pH of 3.4 to 3.6 compared to a pH of 3.4 to 3.6 plus drift up to 3.7 to 3.9 for five minutes. You have not seen that kind of study?

A. I have not seen it.

MR. LOEB: Objection to form.

THE COURT: It's not the clearest question, Mr. Hales.

MR. HALES: I will try it again.

BY MR. HALES:

Q. So have you seen any study anywhere, whether what was submitted to the Patent Office, any of the references you've identified for teaching away or anywhere elsewhere somebody compared the stability of a formulation that was at 3.4 to

3.6, right, for its life compared to one that was 3.4 to 3.6 throughout its life except for a five-minute time in the range 3.7 to 3.9?

A. I have not seen that study.

Q. Okay.

MR. HALES: No further questions, Your Honor.

THE COURT: Thank you. Ms. Wu?

BY MS. WU:

Q. Dr. Kirsch, nice to see you again.

A. Nice to see you.

Q. You have not been proffered as an expert in biostatistical methods and statistical analysis; right?

A. I have not.

Q. You don't have any degrees in statistics?

A. I don't have a degree in statistics.

Q. Do you agree that Dr. Marais is an expert in biostatistical methods and analysis?

A. Yes, I guess.

Q. Now, you've relied on Dr. Marais' statistical analysis in one of your slides; right?

A. Yes.

Q. Dr. Marais' statistical analysis is sound and reliable?

A. The statistics is sound and reliable. I have some question about how that data was compiled for that analysis.

Q. **You didn't mention any of that in your direct, did you?**

A. **I think I did mention it. That was my recollection, that I did -- I commented that he combined studies that were outside of the -- of the declaration studies.**

Q. **But you recall there was work that Dr. Winter did to show the formulations that were pooled were comparable; right?**

A. **I believe that he attempted to address that topic. Again, I don't know that I agreed entirely with his, with his assessment.**

Q. **You didn't present any details on those disagreements with regard to the formulations, did you, during your direct?**

A. **Not during my direct, no.**

Q. **So if we could have your slide PDX-6.25, please. And I think you pointed to the one result at the bottom of the slide; right?**

A. **Yes.**

Q. **And there are actually 18 results here that Dr. Marais presents?**

A. **Yes.**

Q. **The other 17 show that there is no statistical significance; right?**

A. **Yes. I mean, if one judges statistical significance**

strictly on the .05 cutoff now, you know, that is a choice that a statistician makes. There certainly are some of the results in which the P values tend to approach that region, but there are no others that are below the .05 P level.

Q. You yourself used that .05 P level in your analysis; right?

A. I have, yes.

Q. And what do you understand from Dr. Marais' results here except there is no statistical significance between formulations at pH 3.6 and pH 3.7. Right?

A. Well, I mean, that -- I don't agree with that analysis. My analysis shows there certainly is a difference.

Q. Okay. But Dr. Marais is showing, you understand that he's showing the results that you show the Court in your slide demonstrates that there's no statistical significance between formulations of pH 3.6 and 3.7?

A. I'm sorry. Say your -- ask the question again.

Q. I will. The data you presented, which was originally Dr. Marais' data, shows that there is no statistical significance between formulations at pH 3.6 versus pH 3.7; right?

A. If you mean Dr. Marais' analysis data that he is using, that's correct. That's not my data.

Q. Okay. But you cited this data; right?

A. What?
Q. You cited this data in your direct; is that correct?
A. I cited it as a comment on -- on what Dr. Marais has shown me, yes.
Q. I just want to make sure.
A. I'm just not taking possession of that data. It's not my data that was used in this or the analysis that was done. It's not mine.
Q. But I want to make sure I understand your reading of this. Is your reading of this also that pH 3.6 and pH 3.9 have no statistical significance difference?
A. Again, I don't agree with the analysis that was -- that all of the details of the analysis that he did, but his conclusions, his conclusions based on the P values was that it was only one that showed statistical significance.
Q. Now, table ten is not the universe of statistical analysis that Dr. Marais performed in his report; right? In this report that you pulled?
A. That's correct.
Q. All right.
MR. LOEB: Objection. Outside the scope of his direct.
THE COURT: I think it goes to credibility. Attempt to update.
BY MS. WU:

Q. So I would like to just pull up the front of Dr. Marais' September 11th, 2020 report, which I believe you pulled this table from.

Do you recognize this cover page?

A. I've seen a lot of cover pages. I believe it's from his report, September 2020.

Q. Would it be helpful if I handed you his report? I wasn't planning to do this. It's not in the cross binder.

A. You can show me.

Q. Okay. Why don't I do that.

MS. WU: May I approach, Your Honor?

THE COURT: Sure.

BY MS. WU:

Q. Is this a report that you pulled Table 10 out of? If you take a look at page 26.

A. Yes.

Q. Now, I just want to direct you to a section on page 17. I just want to direct you to a title of a section. This is again on page 17. Are you there?

A. Okay.

Q. Okay. So Dr. Marais, do you see that he has a whole section about the stability of vasopressin formulations at the pH level of 3.8 claimed in the patent-in-suit is not statistically significant, significantly different from the stability of formulations at the prior art pH of 3.6?

MR. LOEB: Objection. Hearsay.

MS. WU: I'm asking if he says that.

MR. LOEB: Because I know what your next question is.

THE COURT: The objection is overruled.

BY MS. WU:

Q. So, Dr. Kirsch, you've reviewed Dr. Marais' opinions about how there's no statistical significance between pH 3.6 and 3.8 formulations; is that it?

A. Yes, I have reviewed it.

Q. Okay. Now, I want to take a look at what the inventors said about that data. If you could turn with me to cross exhibit binder DTX-69, please.

Do you have it?

A. Yes, I have it.

Q. Now, this is a declaration that you testified about?

A. Yes.

Q. It was by inventor Sunil Vandse?

A. Yes.

Q. If I could direct your attention to paragraph 14, please.

A. Okay.

Q. Do you see it states in the middle, "At 40 degrees C, pH 3.6 and 3.8 provided similar stability for vasopressin, (FIGURE 4).

Do you see that?

A. Yes, referring to the decrease in assay results.

Q. Would you agree that named inventor, Mr. Vandse's statement that pH 3.6 and 3.8 vasopressin formulation provided similar stability is consistent with Dr. Marais' opinion of no statistical significance?

A. No. I believe that what Dr. Marais did was somewhat different than this. He didn't compare 3.6 directly to 3.8 is my recollection. But in any case, when he is saying stability, he's specifically in this document, he specifically means the loss of vasopressin, so he then goes on to comment on the appearance of impurity as well, and there he sees that there is a difference and then makes a conclusion based on the overall behavior using both of those measures.

Q. Well, Dr. Kirsch, let me just point you to page 20 of Dr. Marais' report so we can have it straight as to what Dr. Marais did.

A. Okay.

Q. Do you see on page 20, he does a regression analysis of percent total impurities of test formulations at pH 3.6 and 3.8 stored at 40 degrees Celsius?

A. Yes, but, you know, I would have to review the report to see what data he's looking at, because clearly, he has more data than what was presented in the declarations when

he makes that analysis.

I mean, if you look on page 18 --

Q. But, Dr. Kirsch, we can agree that his analysis was consistent with the inventors' analysis, right, with respect to 40 degree vasopressin assay?

MR. LOEB: Objection, Your Honor. That is hearsay.

THE COURT: Overruled.

THE WITNESS: So your question again?

BY MS. WU:

Q. Dr. Marais' analysis is consistent with the inventors' analysis that at 40 degrees, the vasopressin assay for 3.6 and 3.8 pH formulations are similar, not statistically significantly different?

A. Yes.

Q. Thank you.

All right. I would like to switch gears, please. I'd like to go to JTX-2, which is the '209 patent. I think you are very familiar with that patent. In particular, column 12, starting at line 17.

THE WITNESS: This is in a different binder?

MR. LOEB: Counsel, which binder?

MS. WU: I believe it's in the direct binder.

MR. LOEB: Oh.

MS. WU: It's the patent.

MR. LOEB: Okay.

MS. WU: Yes.

MR. LOEB: Which JTX?

MS. WU: JTX-2.

BY MS. WU:

Q. All right, Dr. Kirsch. You've seen this disclosure in the '209 patent about a non-limiting example of a comparison formulation; right?

A. Yes.

Q. And you agree that the non-limiting comparison formulation that is discussed in this column is that it's Original Vasostrict?

A. I'm not really sure about that.

Q. Okay. Well, let me help you out then. Let's take a look at your cross binder. We have in that binder the deposition testimony of Sunil Vandse. I'm going to take a look starting at page 260.

Do you see on page 260, is there's a question being asked about a non-limiting reads, of comparison formulation, quoting the patent?

A. Yes, I see that question.

Q. And you see that the question that reads, "and that is not a formulation you and your co-inventors invented, correct?" And the answer is, "Correct."

Do you see that question and answer?

A. **Yes.**

Q. **And then after that there is a question about the formulation was known in the art before your invention and the witness says, "that was the approved formulation."**

Do you see that?

A. **Yes, I do.**

Q. **And the original approved formulation of Vasostrict; is that correct? And Sunil Vandse says that is correct.**

Do you see that?

A. **Yes.**

Q. **Okay. Let's go back to column 12 then of the patent.**

So you agree then with the inventor here, that column 12 is about the original Vasostrict formulation?

A. **That's what the inventor identified it as, that's correct.**

Q. **Now I want to go down a little bit lower in that disclosure. Go down a little bit lower beyond -- oh, I guess we have that highlighted. Yes. It's the bottom line that's highlighted.**

Do you see that it talks about a pH of about 3.4 to about 3.6?

A. **Yes, I see that.**

Q. **And I think you provided opinions before that when you talk about the term "about," what happens is, according to you, a POSA would give rounding rule, and then with "about"**

term, it would pass on additional margin around that; is that correct?

A. I don't recall that.

Q. Okay. Maybe take a look at your expert report. I believe this is, I think this is a really big binder that you should have.

If you can take a look at your report, it should be the December 2nd, 2020 report.

THE COURT: I think your reports are in front of you there in the binder.

THE WITNESS: Pardon me?

THE COURT: There are a lot of binders.

BY MS. WU:

Q. It's a big white one. It's a very large white one. Do you not have it?

A. I don't know.

Q. It's on its way. I apologize.

THE COURT: What report are we on?

MS. WU: It's the December 2nd, 2020. It's near the back. It's one of the last ones. It says Kirsch supplemental infringement report, Amneal.

MR. LOEB: I don't have that, counsel.

MS. WU: Oh.

BY MS. WU:

Q. Alright. It's a really big binder. Did you find it?

A. **No. What am I looking for again?**

Q. **You're looking for your December 2nd, 2020 report. It's a supplemental infringement report that Amneal -- for me it's one of the last ones?**

A. **I think, I think I've got it here.**

Q. **Alright. And once you're ready, I would like you, if you can, navigate to paragraph 11 that's on page 9.**

So I think in this paragraph, you are providing an opinion on a previously asserted patent. It's the '223 patent.

Do you see that?

A. **Yes, I see that.**

Q. **And in that patent, which, again, is no longer asserted, there was a claim limitation about 3.7 to about 3.8.**

Do you see that?

A. **Yes.**

Q. **And so what you say and that you care about, that the pH range can be broader than 3.7 to 3.8, allowing some margin around 3.7 to 3.8 when also applying normal rounding principles.**

Do you see that?

A. **Hang on. I see that. Yeah. I mean, it could -- and I think that the way it's written here is that it can --**

Q. **Okay.**

A. It can be broader than -- than the rounding will allow.

Q. All right. That's how I read it, too.

Let's go back to column 12 of the patent and apply your opinion there.

So would you agree with me that about 3.4 to about 3.6 means something more than 3.64, because it's something more than merely rounding; right?

A. I don't -- I don't agree with that. It says that it can be, so you would need some other guidance that would allow you to discern what that, what that term about means in this case.

Q. So it's your opinion today that about 3.6 in the patent does not include 3.65; is that right?

A. That the patent has a three-point --

MR. LOEB: Objection, Your Honor. That is not in the claims at issue.

THE COURT: She's not asking about the claims. She's asking about column 12, the words about 3.6, unquote, and it is a fair question. I would like to hear the answer.

BY MS. WU:

Q. Dr. Kirsch, do you understand the question?

A. Please ask the question again.

Q. Is it your opinion today that about 3.6 does not

include 3.65?

A. I think that there would be -- have to be some additional clarification in terms of what the about would mean in this. It doesn't have any particular meaning in my estimation. I mean, it doesn't -- it doesn't tell me what the about means.

Q. Oh, I'm not asking you to quantify the breadth of the "about." That's not what I'm trying to do at all. We agree that 3.6 includes under your opinion 3.64; is that right?

A. 3.64, yes.

Q. And about 3.6. So that's something more than 3.64; right?

A. Not necessarily. It could simply 3.64. It could be. I would need additional information to make that. There has to be some clarification about what the about meant.

Q. Okay. Your testimony today, about 3.6 does not include 3.65; right? That's your testimony today?

A. No, it's not. It's that it's unclear as to what it is.

Q. I'm not sure I'm following you. So, again, I think the baseline here is 3.6 includes 3.64?

A. That's correct. If it simply says 3.6, that meant one would assume with rounding it meant 3.64. If it says about, then additional information is needed to understand what

about means in this context.
Q. Okay. But, again, I want to be fair. I want to give you your time. Your testimony today is that about 3.6 does not include 3.65; right?
A. That's not my testimony. I don't know what that term means.
Q. So if I were to ask you, Dr. Kirsch, you're a formulator. You can represent the views of a POSA, you're reading column 12. You see addition disclosure of a comparison formulation, which is a prior art formulation. What does about 3.6 mean?
A. Without some other information, perhaps some data that shows what they were -- what they were talking about, it would be hard to know what that means. It's unclear.
Q. Alright. Well, Dr. Kirsch, this isn't the first time we've discussed this topic; is that correct?
A. Perhaps.
Q. I think we spent some time during a deposition last year.
Do you recall that?
A. Specifically, no.
Q. I know I'm not that memorable. Okay.
So if we could get to page 70 of your deposition, I think the transcript is --
THE COURT: Hold up. There's an objection.

MR. LOEB: I don't have the transcript, Your Honor.

MS. WU: It should be in the same binder. It's in the expert report binder.

MR. LOEB: The expert report --

MS. WU: And deposition binder. It's in the front this time.

BY MS. WU:

Q. If you could look at page 70, do you recall --

A. Excuse me. I'm not sure which transcript. There are two transcripts there. Which one are we looking at?

Q. It should be the second tab. It should have a label 2020, December 16th, 2020, Kirsch transcript, Amneal?

A. Thank you.

Q. It should be near the front, at least in my version.

THE COURT: 16? Yes. December 16th?

MS. WU: December 16th, yes.

THE COURT: Okay.

MS. WU: Page 70.

BY MS. WU:

Q. And if you want to start reading at page 69, Dr. Kirsch, I was asking you about the comparison formulation of column 12 of the patent; right? Do you see the testimony?

A. Yes.

Q. And we finish a line of questioning with you saying,

"it's fair to say it could have a pH of 3.65," right?
A. Yes.
Q. And so I think previously, you opined that there was no overlap between the prior art and a pH of 3.4 to 3.6.
Do I have that right? Sorry. I messed up my question?
There's no overlap between the prior art range of 3.4 to 3.6 and the claimed range of 3.7 to 3.9. Did you give that testimony?
A. I did.
Q. Okay.
A. And my statement is that it could have. I didn't say that it does. Again, this is a matter of how the term about is understood.
Q. So the POSA reading the column 12 disclosure in the patent, they would understand, at least based on your expert report opinion, that there would be some margin beyond 3.64 and there would be an exact overlap between the claimed range and the prior art; right?
A. I don't think I've ever made those declarative statements in that way.
MS. WU: I have no further questions.
THE COURT: Thank you. Any redirect?
MR. LOEB: Very brief, Your Honor.
Could we have Dr. Kirsch's slides, please?

Could I please have slide number 23?

REDIRECT EXAMINATION

BY MR. LOEB:

Q. **Do you remember Mr. Hales asked you a few questions about your slide PDX 23?**

A. **Yes.**

Q. **And specifically, he was focused on a comparison between 3.9 pH and 4.0, right here (indicating)?**

A. **Yes.**

Q. **And he asked you about whether that there was a difference in the impurities in the calculations that you did between 3.9 and 4.0.**

Do you recall that?

A. **I recall that.**

Q. **Right. And as is his right, he cut you off when you wanted to explain. You said that's only part of the story.**

What's the rest of the story?

A. **Well, there are two -- there are two points of analysis that -- that's used in identifying the criticality range and the other -- this is one of them. And then the other one is the loss of such -- the loss of vasopressin.**

And if one looks at the loss of vasopressin and then the data at pH four is significantly less, there's significantly less stability than what one can see in the claimed range.

So if you take those two pieces together, and I think that, you know, that's even described in the patent and -- not in the patent, but in the inventor's comments, or the inventor's assessment of their data, that you combine the loss of vasopressin with the appearance of impurities and you come to the -- the critical range, and 4.0 is outside the critical range not because of the appearance of impurities, but because of the loss of vasopressin.

Q. So does the fact that there are four values worth in the range of 4.0 or 4.1 where your analysis didn't show the statistical significant difference as compared to the claim range, does that affect your overall opinion whether or not the claimed range of 3.7 to 3.9 was critical?

A. No. If one takes into account both of those data, then 3.7 to 3.9 centered around 3.8 is the critical range.

Q. And do you recall just before Mr. Hales was asking you about this, he's asking you a lot of hypothetical questions.

Well, I'm not going to ask about those, but, rather, he was asking you -- he tried to ask you whether you were equating statistical significance with criticality.

And what I was wondering was, in your presentation, did you show any, or discuss any real world differences between the products which have been made and

tested over their whole life that have pH's within the claimed range, pH 3.7 to 3.9, as compared to, for example, original Vasostrict which has a lower pH?

A. Yes.

Q. And what was that?

A. So I did an analysis of the data for original Vasostrict and Eagle's product and the reformulated product based on stability data that was available for 25 degrees and found that there were statistical differences between those three formulations.

Q. And did you --

THE COURT: Hold up. Yes, sir?

MR. HALES: If he's going to -- there was no testimony of any statistical differences in that context about the comparison of reformulated Vasostrict to original Vasostrict?

THE COURT: So everything is beyond the scope?

MR. HALES: Correct.

MR. LOEB: Your Honor, there actually was:

MR. HALES: If the witness is suggesting like PDX-6203 which is on the screen, no.

MR. LOEB: Your Honor, it has nothing to do with the slide.

THE COURT: Right.

MR. HALES: I think he had a percent difference.

There was no statistical analysis in the slide.

MR. LOEB: He did testify about that.

THE COURT: I'm going to let it go for right now.

BY MR. LOEB:

Q. **And what about the data concerning the shelf life of original Vasostrict versus reformulated Vasostrict? Does that show a real-world difference between a product with a pH of 3.6 and a product with a pH in the range between 3.7 and 3.9?**

A. **Well, they were estimated shelf life calculations that were done, which showed a difference in the estimated shelf life for reformulated Vasostrict.**

Q. **Would that difference matter in terms of the quality of the product?**

A. **Well, one could get an extended room temperature shelf life in all likelihood as we heard earlier today based on that data.**

MR. LOEB: Could we please have DTX-360 at page 25.

BY MR. LOEB:

Q. **Alright. Yes. Do you recall Mr. Hales asked you a bunch of questions about the impurity data that Par collected for batch number 788435?**

A. **Yes.**

Q. **Here is the focus. If memory serves on the twelve month column.**

A. **Correct.**

Q. **And he asked you to add up those impurity levels?**

A. **Correct.**

Q. **And he asked you how the -- those impurity levels compared to the claim impurity level?**

A. **Correct.**

Q. **Did you do any calculations? Did Mr. Hales ask you to do any calculations that go to the stability, in other words, the rate of impurity formation for lot 788435?**

A. **He didn't ask me to do that.**

Q. **All right. And is your criticality opinion founded on levels of impurities or something else?**

A. **Well, it centered on the rate of the impurity appearance. It -- stability is the rate issue. It would change over time.**

Q. **So does the data and the calculations that Mr. Hales asked you to look at, to do here, tell you anything at all about whether this batch, which was at pH 3.6, had stability, which is comparable to a formulation within the claim 3.7 to 3.9 range?**

A. **No.**

MR. LOEB: No further questions, Your Honor.

THE COURT: All right. Thank you.

All right. Thank you, Dr. Kirsch. Wait. Sorry. I forgot. I had a couple questions for you.

THE WITNESS: Okay.

THE COURT: What do you understand the meaning of statistically significant to be?

THE WITNESS: Well, it has a general understanding that there is some level of disagreement between values that are compared and that can be evaluated by statistical tests and in most, you know, in most cases when we do this, you set forth what the -- what the accepted -- what the level is for statistical significance.

And it's very common that the level for statistical significance is the P level at .05. I mean, there certainly are instances where --

THE COURT: Surrounding. Is that what you mean when you refer to P level? What do you mean by P level?

THE WITNESS: No, no. The P level is the probability that the differences that you see are -- are random and not are actually.

THE COURT: Is it a justification for rounding?

THE WITNESS: No. Rounding is like a different -- the rounding is a different issue. So the rounding has to do with how you interpreted numbers that have greater or lesser precision.

So --

THE COURT: I guess I was thinking the why we have rounding in the first place, because they do the same kind of assumption about a P level being .5.

THE WITNESS: No, no.

THE COURT: It's not. All right. What is confidence level?

THE WITNESS: Well, there's a couple of different kinds of confidence levels, but the ones we've been talking mainly here have to do with the -- if one were to -- 95 percent confidence level, meaning that if one were to do the same experiment a hundred times, that 95 percent of the time, the results would be within some range and that is the 95 percent confidence limit.

THE COURT: And do you correlate statistical significance with confidence level? Two discrete concepts? Do you relate them? If so, how?

THE WITNESS: No. They are -- they are connected. One can select different confidence levels. One can have one-sided confidence level, a two-sided confidence level and for different types of analyses, people sometimes use different confidence levels.

So, you know, it's very typical to use the 95 percent confidence level, which corresponds to a P level of .05, if you will. But one could choose a different

confidence level. So, for instance, in the assessment of bioavailability, the FDA has evaluated the comparison which is not within the 95 percent, it's something broader than that in order to evaluate bioavailability.

THE COURT: Okay. What's the difference in your mind between synthetic -- synthesized, I should say, vasopressin and any animal-derived vasopressin? Why is it significant?

THE WITNESS: Well, let me give you an example. I mean, my first job in the industry was to work on the development of recombinant protein, which was made by a biosynthetic process. It was fermentation and production from bacteria, the first recombinant protein to go on to the market. Previous to that, it had been derived from animal sources. It was extracted from dog pancreas.

And our whole effort there and it lasted for some number of years was to identify formulations in which we would use the recombinant insulin in similar formulations to what had been used for animal derived, because there were differences between the properties of the animal derived in solution and the recombinant insulin and these had to be evaluated.

THE COURT: But what's the difference here with vasopressin?

THE WITNESS: Well, I mean, certainly, one of

the differences would be in the impurity profiles that are associated with the animal derived versus synthetic. I mean, if one gets the protein from an animal source, then what you do is extract in some way the fraction of the protonated material, which would -- which would contain the vasopressin, and then you have to purify that.

The extraction and purification would lead to --

THE COURT: I'm trying to understand. I'm trying to say is it a molecular structure? You basically treat it as, that's an animal derived, this is synthetic.

THE WITNESS: Okay.

THE COURT: I'm not going to pay attention to the Lithuanian article and I didn't really get to hear why.

THE WITNESS: To a certain extent, it has to do with the impurity profile that you get. So the impurities that are associated with the extraction purification process are different than those that you -- that you get from a synthetic manufacturing process. There are different chemicals and different solvents involved and there's a different product.

THE COURT: Is there something about vasopressin particularly that makes you conclude that you wouldn't, a POSA would not have looked to an animal derived product? I don't know whether to call it product, but an

animal-derived --

THE WITNESS: Yes. It's very difficult to look at the source of the API and then to develop the final product from the API that comes from a particular --

THE COURT: Here's the thing. I've got other case I've had, so that's why I'm asking you where POSAs have relied on animal derived proteins --

THE WITNESS: Mm-hmm.

THE COURT: -- in formulating synthetic protein I guess it's called.

THE WITNESS: Right.

THE COURT: So in other cases, it seems like they've done it. You said, we don't do it, and I'm just trying to understand, is it specific to this particular type of peptide? Is it particular if it's vasopressin? What is it that you would ignore or would not if you looked to the Lithuanian article in this particular instance?

THE WITNESS: Yes. It's the manufacturing of the API that would create different sets of problems, different sets of issues for the animal derived versus the synthetic. I mean, if you could get, you know, a totally pure -- I mean, if it's just the molecule, the molecules are the same, but it's what comes with the molecule that is different.

My recollection is the Lithuanian letter patent,

the impurity levels in that can be up to five percent, so there's a significant amount of impurities that are present. They're different impurities than what one would get from a synthetic process because the method of production, the method of making that -- that chemical is highly different.

THE COURT: All right. Can I see PDX-6-27? PDX-6-27, one of your slides. Yes, okay.

So you did a comparison here of Eagle's SVA2 and 3 with the registration batches. Is that right?

THE WITNESS: That's correct.

THE COURT: Why did you pick SVA2 and SVA3?

THE WITNESS: Well, because SVA1 had an excursion outside the -- outside the 3.4 to 3.6 range, so just to make it clean and only look at the data which came -- in which all the pH values were within that 3.4 to 3.6 range.

THE COURT: And why not SVA7 or 9 or 11? That's one. I get one.

THE WITNESS: Yeah. I don't really have a good reason why they picked 7 through 11.

THE COURT: Okay. Oh, the -- step on back to the animal derived. You said you were talking about the impurities?

THE WITNESS: Mm-hmm.

THE COURT: Does the impurity level affect

stability?

THE WITNESS: No.

THE COURT: Okay. Thank you.

Any other questions?

MS. WU: Your Honor, I wasn't sure. I want to seek your guidance about the Marais report. We referred to it sometimes. I really hadn't intended to put it into, admit it as an exhibit.

THE COURT: You may step down, Doctor. You're excused. Thank you.

(Witness excused.)

MS. WU: I was wondering if it would be help helpful for you to have a reference.

THE COURT: Are you asking for it to be admitted?

MS. WU: Well, we could label it as a demonstrative exhibit.

THE COURT: I don't think it works that way.

MS. WU: Okay.

THE COURT: What are you asking?

MS. WU: I think the title and everything should be in the Q&A. I'm just wondering with everything else, there's something that is a backup to see what the document is, so if it's helpful, on but otherwise, I'm happy with the information in the Q&A.

MR. BLACK: Just so we're clear, Your Honor, that report -- I just want to make sure it's not going to be admitted.

THE COURT: It's not admitted.

MS. WU: Can we mark it as a Court exhibit? Would that be helpful?

THE COURT: It is not going to be helpful because -- that's why I asked Ms. Wu. I'm not trying to be cute. I'm trying to be -- it wasn't marked. Normally, it would be marked maybe to facilitate references to it during the trial, but at the end of the day, we have a record. That's all I'm going to be looking at, is the record. And you didn't move to admit it, so I didn't have to address whether I would admit it. And we have dialogue.

MS. WU: Yes.

THE COURT: I mean, look, candidly, the way you touch upon issues through the entire trial which have to do with rounding and just how rounding works with this case and the implications of it, and we're talking about 3.6 and 3.7 and whether they abut, whether they overlap and experts seem very comfortable rounding in certain contexts and then we're parsing 3.64 versus 3.65.

So is it an issue I was curious and it bugged me the whole trial, but we've got testimony and that's in the evidence. So anyway, thank you.

Anything else?

MR. LOEB: I was just going to make a small point about the question you were asking Dr. Kirsch about why we didn't address the SVA7, et cetera.

THE COURT: Are you going to testify?

MR. LOEB: No, no. This is a factual issue outside the record. His expert report was long before Eagle had produced the stability data, which is -- which he performed this analysis. So it wasn't a choice of his not to look at it.

MR. HALES: To be clear, there have been multiple supplemental reports from Dr. Kirsch since the data went out for SVA --

THE COURT: Look, in a way I actually was curious personally. I mean, I want to know whether -- personally, what I want to know it -- basically, what I want to know is did he pick these because these were good numbers for him? So even that is not far off. So, and I was kind of curious. I didn't know why he picked the numbers. That's why I was kind of curious.

MR. HALES: The argument that we would make is that he did.

THE COURT: Okay. Then you can make that. We'll get to that, but that's fine.

Okay. So you've finished with him. What's

next?

MR. BLACK: We're done.

THE COURT: You're done? You rest?

MR. BLACK: Plaintiffs rest.

THE COURT: Okay. Thank you. So we're finished?

MR. BLACK: Yes.

MR. HALES: We're finished, Your Honor.

THE COURT: Okay. So we've got to talk about briefing and I've got to keep that schedule and I'm going to try to move fast.

I've got a couple real quick questions. I mean, you know, let me just ask the plaintiffs. When it comes to paragraph 7 of the inventor's declaration, put aside whether it's true or false.

Would you agree if it were false material, paragraph 7? I mean, the Patent Examiner has said basically -- given what the Patent Examiner was led to --

MR. BLACK: It would be material to removing the April 2014 --

MR. LASKY: I mean --

THE COURT: If you don't want to answer and you want to think about it, I'm trying to also recognize what's --

MR. BLACK: I think the main issues -- I

understand. I wanted to be careful what I say. I understand what you are saying about materiality, but the bigger issue is if it's material, there has to be -- we've got the intent issue and you have to be able to read the declaration.

THE COURT: I get you on that.

MR. BLACK: If it's only material, it's not material to this case. It's not material to the patents in this case because what it did was remove the April 2014 label as prior art, but the April 2014 label is admitted prior art in this case and therefore cannot be material as a matter of law to the patents here unless you let them claim materiality, establish intent, render the '239 unenforceable and then say on some other theory that the conduct flows all the way through to the asserted patents, and then after all of that, you use your equitable discretion and determine that the correct remedy is to invalidate or render unenforceable all three patents rather than just the '239.

THE COURT: Okay.

MR. HALES: Your Honor, I don't know if you want to have a reaction to that or just ask questions of the side you want to ask.

THE COURT: I think for you, my question would be subject matter. Is that a term of art?

MR. HALES: Subject matter?

THE COURT: Yes.

MR. HALES: I think -- well, I don't know if it's a term of art per se, but in this context, I think, yes, the subject matter that the Examiner relied upon, I think it pretty clearly refers to that information which was the part of the rejection that is being applied. Right? So I think that's a fairly clear sentence certainly in this context of information that the Examiner identified.

THE COURT: And that definition includes a drug formulation that has been around for almost a century, for the administration of a drug that has been around for a century. Right?

MR. BLACK: The drug had been around for a long time for sure.

THE COURT: That's been encompassed by your definition of subject matter. You know, do you really think that anybody thought that the inventor was purported to have come up with the idea that you've got to administer vasopressin when it has been around for a hundred years?

MR. HALES: The Examiner may not know that. That's the reason that when the Examiner has questions and asks for information, there's a duty to be truthful.

The other thing is once you see that happening, once that's removed, now the Examiner is trying to stitch together three references and tell us the formula that puts

it together.

So the significant impact in taking one reference that has everything and removing that from her analysis and then having her go try to find things here and there. So I think there is a very meaningful impact for that.

And just quick reaction to Mr. Black's comments about, I think he said as a matter of law irrelevant. I think it's 100 percent the opposite. The fact that it's admitted prior art in this case would demonstrate the materiality before the Examiner.

THE COURT: Okay. Well, a lot of interesting things to think about.

Do I have to get to criticality? Do I have to get to criticality in this case?

MR. BLACK: You don't, actually.

THE COURT: Assuming I don't say there's no infringement and I get to validity at all, do I have to decide, do I have to address it? In other words, don't say it because, you know, assuming I'm doing a validity analysis -- --

MR. BLACK: I will give you a precise answer. It's their burden of proof by clear and convincing evidence. If they didn't present a competent invalidity case that is persuasive by clear and convincing evidence, we actually

don't have to put any evidence on at all.

In this case, their assertion is that because there's an overlap or there's an abutting range, that a presumption applied. We actually have an overlapping range, which is a tougher standard to meet, because the 2.5 to 4.5 includes 3.7. But put that aside.

The presumption would only arise if all of the claim elements were covered and the impurities were not dealt with in the -- in their assertion about abutting. So they failed to that point.

The second point though is we had evidence that was presented to the Patent Office. This is an issue the Patent Office reviewed. They've have reviewed criticality over 2.5 to 4.5 with a lot of data in front of them and rendered a decision. That decision like every other decision made by the Patent Office is entitled to a presumption of validity and not just the basic presumption you'd get under 35 U.S.C. 282, but the real world effect that you get when an Examiner has actually looked at something and made a decision.

So they needed to put on a case that was persuasive enough to persuade you by clear and convincing evidence that the Examiner was wrong about her decision. Even if you get beyond all of that and think it's a horse race, the only evidence in the case about other secondary

consideration beyond criticality came from our expert, teaching away.

We had the FDA biopharmaceutics review, which even Dr. Park admitted is one of the very -- the very first place that somebody would look if they were going to make a vasopressin product. Just remember, what we're doing here is that the POSA, make a vasopressin product. They look at the art and they decide what we do about pH.

Go to the FDA. The FDA says 3.4 to 3.6 and, in fact, don't go outside that range. End of story. That's the reality.

So that teaching away evidence is actually sufficient to overcome any presumption they've come up with, but in total, that's it. They bear the burden by clear and convincing evidence, and if Dr. Park was not persuasive --

THE COURT: I've written a little bit on obviousness, not on criticality. I don't buy into the there's a presumption and then we get to the secondary considerations to rebut the presumption. I think it's all considered in totality.

MR. BLACK: I agree, Your Honor.

THE COURT: I think the Federal Circuit has cases to say what you just said, you know, but they've got case that say don't do it.

MR. BLACK: I gave them the benefit of the doubt

that if there is a presumption.

THE COURT: Yes, okay.

MR. BLACK: I don't think there should really be a presumption here because the Examiner looked at the evidence.

THE COURT: Okay. What do you think?

MR. HALES: I think you do need to get to criticality.

THE COURT: Now, why? In fact, don't you have a better case without me getting to criticality?

MR. HALES: I think we have both. There are two scenarios. When you have either overlapping, abutting or close range, there's a difference.

THE COURT: So you think I've got to address the overlapping ranges in order to find obviousness?

MR. HALES: In one scenario, in one scenario theory. And there's a path where you get there without criticality. There's a pathway there, too.

THE COURT: I thought you opened up by saying I had to get to criticality.

MR. HALES: Well, you have to consider both to decide against us, I think. Right? You could go on one and not do the other, I guess to that point.

But in the overlapping range scenario, this is not like the secondary considerations. We accept that I

think we're fine with the premise that it means obviousness and traditional analysis.

Secondary considerations, you don't have to do the prima facie case first and then look at secondary considerations only in that sense, but when you were in the overlapping, abutting, close range ratio, that establishes a prima facie case that essentially says when the prior art is so close that it just differs by a range where you don't expect that closeness of range to make a meaningful difference, then the burden does go to the patentee and they have to come back to say, hey, improve or establish.

I mean, the burden ultimately is on us, of course, but they have to show that there is this slightly different range of the value in question is critical compared to everything else outside it.

So in that pathway, because of the closeness of the range, the abutting range, they have to make that criticality showing. In the standard 103 context, you wouldn't have to look at it that way.

And we would say, we would just make a traditional case, which is we've established how close the prior art is. There's virtually no difference. We'd have to show that it was already happening and you could just get there through that pathway as.

THE COURT: Then I have to deal with unexpected

results and teaching away.

MR. HALES: They can make teaching away argument in either scenario. I mean, they would have to say the teaching away, they could use criticality or teaching away to deal with commensurate in scope.

THE COURT: And they put on unexpected results.

MR. HALES: They could do that, too. They could do those things. They can do that in either scenario. But the important thing that we have to factor in here is claim scope.

All of this, teaching away, criticality evidence, unexpected results have to be commensurate with the claim scope. And one of the things that the Examiner, that Mr. Black talked about, the Examiner didn't have anything indicating that there was going to be the drift theory applied. Right? The Examiner, everything we see in the record is looking at information and data about is 3.7, 3.9 critical over other ranges outside that claim scope.

Now, and we know from the admissions of the inventors and others that there is no data and Dr. Kirsch admitted, there's no data in the record at all comparing a scenario where drift exists to one where it doesn't.

So this theory that they've had to advance for infringement, the drift theory, has taken an already very tiny difference between the claimed pH and the prior art or

non-claimed pH and made it even smaller. And the Examiner never had that. That's where our evidence comes in on that point.

THE COURT: Okay.

MR. BLACK: So the evidence is that in the art, the artisan often, probably normally, reports 3.6, 3.7, 3.8, 3.9. They round. The pH meters are often calibrated to do decimal. So 3.6 and 3.7 are going to have their meaning rounded in the context of the case.

With respect to criticality, and we have to show that if they're right about the presumption, and there are a number of reasons why that's wrong and we'll address it in the briefing, but they have to show criticality of 3.7 to 3.9 over 3.6. The that's the way POSAs gather their data. And we've done that.

Marais helped with that. We have teaching away. We have unexpected results. We have an improved product shelf life, real-world benefits from that range. So even if you found that a presumption had arisen, a prima facie case, we have rebutted it with some evidence of secondary considerations, significant evidence on teaching away and unexpected results and real-world benefit and that would be enough on its own with or without criticality.

That's our position and I think that's right and, clearly, he said at the end, it's ultimately their

burden by clear and convincing evidence.

And, look, it's very strange. You have a prima facie case. The ultimate burden is statutory on them. The cases is, as you know, they are somewhat confused about that.

THE COURT: All right. Did you want to say something else?

MR. HALES: No. I think I've covered it.

THE COURT: I like that.

MR. BLACK: One more thing about drift, Your Honor. Their case has drifted as sometimes happens.

THE COURT: And yours has not?

MR. BLACK: And ours has drifted, too, and they've come together in the middle. And one thing I want to point out, Your Honor, is that they keep saying there's drift, there's drift.

The problem is their product is uncontrolled and it drifts and it drifts into the infringing range and it's a narrow band and that has consequences.

THE COURT: Is there any -- do you have any data for post-optimization, a pH reading of 3.7 to 3.9?

MR. BLACK: No, but we have uncontroverted evidence that after release, and even within a couple weeks, their pH, their product will rise by at least four-tenths of a pH unit, and if they get approval, if they insist on

an approval that the right to manufacture and release at 3.64, then they're going to infringe inevitably with this product.

THE COURT: So then you could sue them if there was actual infringement. I've got an ANDA case.

MR. BLACK: You have to make a prediction about what the product on the market would be based on what they are authorized to sell. They've shown you a couple batches --

THE COURT: You show me authorized to sell. I say it's authorized by the FDA and that includes stability specifications. But I will read the briefing.

MR. BLACK: The Tyco case. We'll brief it.

MR. HALES: I think we've covered it adequately unless you have further questions. But we agree, we have a two-part specification. More important, the release and the ability to set the specification. The Ferring case and others are directly on point.

MR. BLACK: And so, Your Honor, just one last point. We have an ANDA case. The jurisdiction of the Court arises originally because of the ANDA case, but we also have a 271(a) straight-up claim. We can't, for declaratory relief --

THE COURT: All right. You might have a claim, but --

MR. BLACK: We would be entitled to, even if you conclude that --

THE COURT: So you're saying basically, 271, a normal declaratory judgment because somebody is about to infringe?

MR. BLACK: Yes.

THE COURT: And yet you're also telling me they don't even have a finalized product.

MR. BLACK: Well, they're close. They're threatening a launch.

THE COURT: This is the same person telling me a month ago, oh, they're never going to get on the market. These guys, can't trust them.

MR. BLACK: They're threatening to launch, they're threatening to launch. We have to take that seriously.

MS. WACKER: Your Honor, Mr. Black has mentioned the Tyco case a number of times now. At the District Court level, Judge Chesler in New Jersey actually granted a 52(c) motion of noninfringement in that case, very similar facts.

THE COURT: I've read other cases that --

MR. BLACK: We'll brief that. Obviously, it's a major issue in the case, Your Honor, with our understanding of that. But I do want to point out the 271(a) issue.

THE COURT: You don't have to point it out.

Frankly, I mean, I'm going to have to brief that now? I mean --

MR. BLACK: There's nothing more -- only in this sense, Your Honor. The difference would be significant for us because on the 271(e) claim, we have mandatory ANDAs not approved. The ANDA would be FDA would not be allowed to approve it.

271(a), what we would be asking for would be more limited. A declaratory judgment that if they sell --

THE COURT: They're going to have jurisdiction and you're telling me they don't have a product. The only reason they have a product as far as I can tell, the only reason this case is being tried -- I guarantee it's the only reason the case is being tried is because it's an ANDA case.

MR. BLACK: You have -- you had jurisdiction at the beginning of the case for both. Certainly at this point, the 271(a) claim is ripe. They are saying they are a couple months from launching.

THE COURT: You're even telling me they don't have a final product. They don't have approval.

All right. I don't know. If you want to brief it, fine, but this is an example -- I mean, you'd better have cases. If you are going to brief it to maintain credibility, you have credibility, but if you are going to

brief it, you'd better have a case that says in these circumstances where literally, less than a month or so ago you're telling me they don't have a product and wondering whether we really -- you know, that you're now saying, oh, I've got ripeness under Article III and the Constitution says to adjudicate a declaratory judgment absent the ANDA statute.

I mean, think about it. If we didn't have ANDA, you would stand up here and tell me this should be a declaratory judgment?

MR. BLACK: Not on the day -- not on the day that that they sent us the P-4 notice. That wouldn't be ripe then. But at this point, it is ripe.

THE COURT: All right. Like I said, everybody take their shot.

So I did want to ask before we cover the last topic I want to get to, which is page limits or word limitations, I do want to ask just out of curiosity because I don't know the law and you both have just posited -- I don't mean by that now it's true, but you both say, hey, this is a situation where we've got a drug that's on the market for almost a century and before the FDA even existed.

And then Par comes in and files an NDA to put that drug through the FDA approval process, and by doing so, claims exclusivity. And I'm fascinated just thinking about

the policy behind it how the law permits that, and it obviously does.

Both sides get a chance. It has nothing to do with the merits of the case. It's just trying to understand how the world works that we could have had all of these drugs that were used for literally decades and we're treating people and all of a sudden we don't.

MR. BLACK: I'm happy to talk about that. I prefer to go off the record maybe on this, because it's not germane to the case.

THE COURT: It's not germane to the case. Can we go off the record?

MR. HALES: I'm fine either way, Your Honor.

THE COURT: Well, if you are fine either way, I'm not going to clear the courtroom.

MR. BLACK: I don't want you to clear the courtroom.

THE COURT: We can go off the record. It won't be part of the record. I won't consider it. I'm just curious.

(Discussion off record.)

THE COURT: We'll go back on. Let's talk about word limitation.

MR. BLACK: We had an order originally in the case that's 7500 words per brief, which we think ought to be

sufficient.

THE COURT: In fairness to them, they've got more to deal with.

MR. BLACK: Okay.

THE COURT: That's the posture they're in. I'm a little sympathetic to that.

What do you think you need, but don't overwrite. Right? I mean, I complimented both sides, because when I was talking to you guys at sidebar, I said I thought Dechert was succinct.

MR. HALES: One question, Your Honor. Is this a one package, findings of fact, conclusions of law brief, or do you have briefs with findings of fact separate in a bench trial?

THE COURT: I probably prefer them separate.

MR. BLACK: Okay.

MR. HALES: And then is there sometimes findings of fact, conclusions of law, so the word limit a combined one, or how do you to do it, because I don't want to overload you.

THE COURT: You probably think more in pages than words. If you were thinking words and you were thinking pages, what do you think you need?

MR. HALES: If it's a brief that we're talking about, 7500 words, 30 pages, that would be fine, but if

we're talking about that extending to the findings of fact and conclusions of law -- the times that I've done that, usually it has been a word limit on the brief and the findings of fact, conclusions of law, I don't have that apply to them. I'm not trying to bury you.

THE COURT: Seriously, if I don't put a limitation on the statement of facts -- seriously, come on.

MR. HALES: I'm not asking for it to be unlimited.

MR. BLACK: And I would think --

THE COURT: Well, actually --

MR. BLACK: It's fine to have separate findings of fact and conclusions of law in the brief. It's going to be rather repetitive. Whatever you want, Your Honor.

THE COURT: So it is repetitive. It's very much repetitive, but 52(a) requires me to set them forth separately.

I find that it makes you pay special attention to citations, because when I read a statement of facts, if there isn't a citation, it's gone. Your facts are gone from the record. If I read it and either my clerk or I find that it is not correctly cited, it's gone. I don't even pay attention to it and that's the advantage.

MR. BLACK: Actually, I was suggesting the other, that we have findings of fact and conclusions of law

and then we wouldn't need a brief, because the brief would just be repeating what's already in.

THE COURT: I wasn't thinking conclusions of law. Conclusions of law, you know, you can do -- you figure it out. Hold on.

I've not really separated out briefs and conclusions of law. That's the same project. The conclusions of law, you can call it conclusions of law if you want. That's your brief, your argument.

MR. BLACK: Okay.

MR. HALES: All right.

THE COURT: All right? So findings of fact. You know what I will do? I might regret it. I'm not going to put a limit on statements of fact and we'll see who does the smart thing.

MR. BLACK: You're throwing down the gauntlet, I see. I see it on the ground. We'll try to pick it up.

THE COURT: And then your briefs, do you think 7500?

MR. HALES: I think 7500.

MR. BLACK: Yes, Your Honor.

THE COURT: That's what we'll do.

And then the schedule. You're going to -- 7500 for validity. You answer, you file them, then you answer and then you file them all with me, the 28th electronically,

a hard copy the 29th by 8:30 a.m. It has to be. No extensions.

MR. BLACK: Yes, Your Honor.

THE COURT: The transcript -- you've gotten dailies. We're going to get you revisions on the transcript -- we'll get you the transcript Wednesday. You can then make your errata sheet by Friday close of business. You're going to have to work, get those erratas done. You've got to submit them to the court reporter.

And incidentally, just so you'll know, I read all the transcripts that go out and I edit myself. I don't edit anybody else. I'm not going to do that here. I am going to wait and do that down the road. I don't think it will affect your briefing.

You get the errata sheet back by the close of business next Friday to the court reporter and she will quickly turn around a finalized sheet easily so that you'll be able to get all the briefs done with the correct citations by July 28th. All right?

MR. BLACK: Yes, Your Honor.

MR. HALES: Yes.

THE COURT: Okay. And then I think that's it.

I do want to say everybody did a great job, and if I was hard on a couple of lawyers at times because it was my confusion or what not. Mr. Lasky, you did a great job.

MR. HALES: Thank you.

THE COURT: Everybody did as well. And then we'll plan on oral argument potentially. We'll wait and see what the briefs look like. But if I had it, I think it would be in August, certainly no later than early September. I'm going to be candid. I know you're all busy. We'll work with you, but we're going to do a quick turnaround. All right?

MR. HALES: Yes.

MR. BLACK: Yes, Your Honor. Thank you.

(Court recessed at 5:43 p.m.)

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